12-19-06

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Brian A. Vaartstra et al.	Group Art Unit:	2815
Serial No.: 09/603,132 Confirmation No. 3538		Examiner:	Eugene Lee
Filed:	23 June 2000	Docket No.:	150.00650102

Title: DEVICE STRUCTURES INCLUDING RUTHENIUM SILICIDE DIFFUSION BARRIER LAYERS

Commissioner for Patents
Mail Stop Appeal Brief-Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We are transmitting the following documents along with this Transmittal Sheet (which is submitted in triplicate):

X An itemized return postcard.

X An Appeal Brief (23 pgs.); Claims Appendix (7 pgs.); Evidence Appendix (1 pg.); Related Proceedings Appendix (1 pg.); Cited Authorities and Documents Appendix (1 pgs.); Copies of 18 cited Authorities and Documents.

X **Please charge Deposit Account No. 13-4895 in the amount of $180.00, for the Appeal Brief Filing Fee.**

Fee Calculation for Claims Pending After Amendment					
	Pending Claims after Amendment (1)	Claims Paid for Earlier (2)	Number of Additional Claims (1-2)	Cost per Additional Claim	Additional Fees Required
Total Claims				x $50 =	
Independent Claims				x $200 =	
One or More New Multiple Dependent Claims Presented? If Yes, Add $360 Here →					
Total Additional Claim Fees Required					

Please consider this a PETITION FOR EXTENSION OF TIME for a sufficient number of months to enter these papers and please charge any additional fees or credit overpayment to Deposit Account No. 13-4895. Triplicate copies of this sheet are enclosed.

MUETING, RAASCH & GEBHARDT, P.A.
Customer Number: 26813

By: _____
Name: Loren D. Albin
Reg. No.: 37,763
Direct Dial: 612-305-1225
Facsimile: 612-305-1228

CERTIFICATE UNDER 37 CFR §1.10::
"Express Mail" mailing label number: EV201878625 US Date of Deposit: December 18, 2006
I hereby certify that the Transmittal Letter and the paper(s) and/or fee(s), as described hereinabove, are being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to: **Mail Stop Appeal Brief- Patents,** Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: Deb Schurmann
Name: Deb Schurmann

(LARGE ENTITY TRANSMITTAL UNDER RULE 1.10)

PATENT
Docket No. 150.00650102

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s):	Brian A. Vaartstra et al.	Group Art Unit:	2815
Serial No.:	09/603,132	Examiner:	Eugene Lee
Confirmation No.:	3538		
Filed:	23 June 2000		

For: DEVICE STRUCTURES INCLUDING RUTHENIUM SILICIDE DIFFUSION BARRIER LAYERS

APPEAL BRIEF

Commissioner for Patents
Mail Stop - Appeal Brief - Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Brief is presented in support of the Appeal filed 18 October 2006, from the final rejection of claims 45-74 of the above identified application under 37 C.F.R. §§1.113 and 1.191.

This Brief is being submitted as set forth in 37 C.F.R. §41.37. An Appeal Brief was previously filed with respect to this application on April 25, 2003, and a fee of $320 was paid. This previous appeal was dismissed, by Order mailed February 27, 2004, before a final Board decision was made on the appeal. Therefore, pursuant to M.P.E.P §1204.01, Appellants authorize a charge to Deposit Account No. 13-4895 for filing this Brief, under 37 C.F.R. §41.20(b)(2), in the amount of $180, which is the difference between the present fee of $500 for filing an appeal brief and the fee of $320 which was previously paid.

I. REAL PARTY IN INTEREST

The real party in interest of the above-identified patent application is the assignee, Micron Technology, Inc., 8000 South Federal Way, Boise, Idaho, as evidenced by the assignment recorded August 27, 1998 at Reel 009418, Frame 0983 of the parent application (U.S. Patent No. 6,197,628, issued March 6, 2001).

II. RELATED APPEALS AND INTERFERENCES

There are no appeals or interferences known to Appellants' Representatives which would directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

Claims 1-44 have been canceled. Claims 45-74 are pending and are the subject of this Appeal (see Claim Appendix).

IV. STATUS OF AMENDMENTS

There are no amendments to the above-identified patent application that have been filed by the Applicants subsequent to issuance of the Final rejection, mailed July 21, 2006.

V. SUMMARY OF CLAIMED SUBJECT MATTER

In one embodiment of the invention, according to claim 45, a semiconductor device structure is recited. The structure of the semiconductor device includes: a substrate assembly including a surface; and a chemical vapor codeposited (e.g., specification as filed, page 9, line 23 through page 11, line 24) diffusion barrier layer over at least a portion of the surface, wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10 (e.g., specification as filed, page 4, line 27 to page 5, line 2).

In a further embodiment of the invention, in accordance with claim 49, a semiconductor device structure is recited. The structure of this semiconductor device includes: a substrate assembly including a surface, wherein the at least a portion of the surface is a silicon containing surface; and a chemical vapor codeposited (e.g., specification as filed, page 9, line 23 through page 11, line 24) diffusion barrier layer over at least a portion of the surface. The diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10. Further, the structure includes one or more additional conductive layers over the diffusion barrier layer

formed of at least one of a metal and a conductive metal oxide, wherein the one or more conductive layers are formed from materials selected from the group of RuO_2, RhO_2, MoO_2, IrO_2, Ru, Rh, Pd, Pt, and Ir (e.g., specification as filed, page 4, line 27 to page 5, line 7).

In another embodiment, as provided in claim 50, a capacitor structure is recited. This capacitor structure includes: a first electrode; a high dielectric material on at least a portion of the first electrode; and a second electrode on the dielectric material. At least one of the first and second electrode includes a chemical vapor codeposited (e.g., specification as filed, page 9, line 23 through page 11, line 24) diffusion barrier layer formed of $RuSi_x$, where x is in the range of about 0.01 to about 10 (e.g., specification as filed, page 5, lines 8-12).

A further embodiment of a capacitor structure is claimed in the present application,. In this further embodiment, recited in claims 52, the capacitor structure includes: a first electrode; a high dielectric material on at least a portion of the first electrode; and a second electrode on the dielectric material, wherein at least one of the first and second electrode includes a chemical vapor codeposited (e.g., specification as filed, page 9, line 23 through page 11, line 24) diffusion barrier layer formed of $RuSi_x$, where x is in the range of about 0.01 to about 10. The first electrode includes a diffusion barrier layer (e.g., specification as filed, page 15, lines 4-5) wherein the diffusion barrier layer of the first electrode is formed on at least a portion of a silicon containing region (e.g., specification as filed, page 17, lines 19-22 and Figure 6: e.g., diffusion barrier layer (285) formed on the sidewalls (261) and bottom (260) of contact opening (259)), and further wherein the first electrode includes one or more additional conductive layers formed over the diffusion barrier layer, the one or more additional conductive layers formed of at least one of a metal and a conductive metal oxide (e.g., specification as filed, page 5, lines 8-12; page 8, lines 3-8)

The application additionally claims embodiments to an integrated circuit structure. The integrated circuit structure of the present invention, as recited in claim 54 includes: a substrate assembly including at least one active device and a silicon containing region; and an interconnect formed relative to the at least one active device and the silicon containing region.

The interconnect includes a chemical vapor codeposited (e.g., specification as filed, page 9, line 23 through page 11, line 24) diffusion barrier layer on at least a portion of the silicon containing region, wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10 (e.g., specification as filed, page 5, lines 13-18).

In a further embodiment, a semiconductor device structure, as recited in claim 57, is claimed. This semiconductor device structure includes: a substrate assembly including a surface defining an opening having an aspect ratio greater than about 1 (e.g., specification as filed, page 15, lines 17-20 and page 15, line 27 to page 16, line 3); and a chemical vapor codeposited (e.g., specification as filed, page 9, line 23 through page 11, line 24) diffusion barrier layer on at least a portion of the surface defining the opening. The diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10 (e.g., specification as filed, page 4, line 27 to page 5, line 2).

In yet another embodiment of the invention, according to claim 60, a further semiconductor device structure is provided. This structure includes: a substrate assembly including a surface defining an opening having an aspect ratio greater than about 3 (e.g., specification as filed, page 15, lines 17-20 and page 15, line 27 to page 16, line 5); and a chemical vapor codeposited (e.g., specification as filed, page 9, line 23 through page 11, line 24) diffusion barrier layer on at least a portion of the surface defining the opening, wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10 (e.g., specification as filed, page 4, line 27 to page 5, line 2).

In a still further embodiment of the invention according to claim 63, a capacitor structure is recited that includes: a first electrode; a high dielectric material on at least a portion of the first electrode; and a second electrode on the dielectric material. At least one of the first and second electrodes has a surface defining an opening having an aspect ratio greater than about 1 (e.g., specification as filed, page 15, lines 17-20 and page 15, line 27 to page 16, line 3), wherein a chemical vapor codeposited (e.g., specification as filed, page 9, line 23 through page 11, line 24) diffusion barrier layer is on at least a portion of the surface defining the opening (e.g.,

specification as filed, page 17, lines 19-22 and Figure 6: e.g., diffusion barrier layer (285) formed on the sidewalls (261) and bottom (260) of contact opening (259)). The diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10 (e.g., specification as filed, page 5, lines 8-12).

An even further embodiment of a capacitor structure of the invention is provided in claim 66. This claim recites a capacitor structure that includes: a first electrode; a high dielectric material on at least a portion of the first electrode; and a second electrode on the dielectric material. At least one of the first and second electrodes has a surface defining an opening having an aspect ratio greater than about 3 (e.g., specification as filed, page 15, lines 17-20 and page 15, line 27 to page 16, line 3), wherein a chemical vapor codeposited (e.g., specification as filed, page 9, line 23 through page 11, line 24) diffusion barrier layer is on at least a portion (e.g., specification as filed, page 17, lines 19-22 and Figure 6: e.g., diffusion barrier layer (285) formed on the sidewalls (261) and bottom (260) of contact opening (259)) of the surface defining the opening. The diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10 (e.g., specification as filed, page 5, lines 8-12).

A yet further embodiment of the invention is recited in claim 69. This claim recites a semiconductor device structure that includes: a substrate assembly including a surface defining an opening (e.g., specification as filed, page 15, lines 17-20), with the proviso that the surface defining the opening is not a silicon containing surface (e.g., specification as filed, page 3, line 26 through page 4, line 2). A chemical vapor codeposited (e.g., specification as filed, page 9, line 23 through page 11, line 24, with respect to M.P.E.P. §2173.05(i); page 7, lines 12-20; and page 13, lines 19-25) diffusion barrier layer on at least a portion of the surface defining the opening (e.g., specification as filed, page 17, lines 19-22 and Figure 6: e.g., diffusion barrier layer (285) formed on the sidewalls (261) and bottom (260) of contact opening (259)), wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10 (e.g., specification as filed, page 4, line 27 to page 5, line 2).

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 45-48 and 54-59 stand rejected under 35 U.S.C. § 102(e) as being anticipated by Komatsu (U.S. Patent No. 5,907,789).

B. Claims 45, 46, 50, 51, 57-59, and 63-65 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuroiwa et al. (U.S. Patent No. 6,239,460 B1) in view of Agostinelli et al. (U.S. Patent No. 5,017,551).

C. Claims 48, 49, 54, 55, and 69-74 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuroiwa et al. (U.S. Patent No. 6,239,460 B1) in view of Agostinelli et al. (U.S. Patent No. 5,017,551) as applied to claims 45, 46, 50, 51, 57-59, and 63-65, and further in view of Lee et al. (U.S. Patent No. 5,872,041).

D. Claims 52 and 53 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuroiwa et al. (U.S. Patent No. 6,239,460 B1) in view of Agostinelli et al. (U.S. Patent No. 5,017,551) in view of Lee et al. (U.S. Patent No. 5,872,041) as applied to claims 48, 49, 54, 55, and 69-74, and further in view of Matsubara et al. (U.S. Patent No. 5,122,923).

E. Claims 60-62 and 66-68 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Kuroiwa et al. (U.S. Patent No. 6,239,460 B1) in view of Agostinelli et al. (U.S. Patent No. 5,017,551) as applied to claims 45, 46, 50, 51, 57-59, and 63-65, and further in view of Lee et al. (U.S. Patent No. 5,897,350).

VII. ARGUMENT

A. Claims 45-48 and 54-59 are not anticipated under 35 U.S.C. § 102(e) by Komatsu (U.S. Patent No. 5,907,789)

It is well established that to sustain a rejection under 35 U.S.C. §102, a single prior art reference has to teach every element of the claimed invention. Appellants maintain the assertion that, for at least the reasons presented below, Komatsu fails to teach every element of rejected claims 45-48 and 54-59, thus, the rejection should be withdrawn.

For anticipation to occur, a prior art disclosure must put the public in possession of the

invention:

> "In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596, 600 (CCPA 1968). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; "***[i]t is insufficient to name or describe the desired subject matter, if it cannot be produced without undue experimentation***." *Elan Pharm., Inc. v. Mayo Found. For Med. Educ. & Research*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) (emphasis added) . . . . A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

M.P.E.P. §2121.01 (page 2100-55, Rev. 5, Aug 2006; emphasis added). Appellants respectfully submit that at the time of the present invention, Komatsu would have failed to provide an enabling disclosure of a chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$. Thus, Appellants respectfully submit that Komatsu does not put the public in possession of the claimed invention as recited in claims 45-48 and 54-59, which recite a chemical vapor codeposited diffusion barrier layer, wherein the diffusion barrier layer is formed of $RuSi_x$.

The Examiner asserted, in the Office Action mailed 10 January 2006, that "[i]n column 22, lines 29-39, Komatsu clearly discloses that the metal silicide layer may be made of silicon and one of many metals including ruthenium. Because Komatsu states in the same paragraph the possible precursors for Ti, W, Mo, Ta, Pt, Re does not preclude the fact that Komatsu specifically states in the same paragraph that the metal silicide layer may include one of many metals including ruthenium." (page 6, item 8, lines 5-10).

Appellants maintain their contention that the mere naming of ruthenium as "one of many metals" that may be used as a metal silicide layer is insufficient to provide an enabling disclosure such that the public was in possession of the claimed invention at the time of the present invention. Although the mere naming of a chemical vapor codeposited diffusion barrier

layer formed of $RuSi_x$ might arguably provide an adequate written description for such a layer, such naming is clearly insufficient to enable the formation of a chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$, for at least the following reasons.

A §102 reference "'must sufficiently describe the claimed invention to have placed the public in possession of it'. . . . '[E]ven if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling'" (*Paperless Accounting, Inc. v. Bay Area Rapid Transit System*, 804 F.2d 659, 665, 231 USPQ 649, 653 (Fed. Cir. 1986), *quoting*, *In re Donohue*, 766F.2d 531, 226 USPQ 619 (Fed. Cir. 1985)). Furthermore, "An enabling disclosure is not 'tossing out the mere germ of an idea' but the provision of 'reasonable detail . . .in order to enable members of the public to understand and carry out the invention.'"(*United States Filter Corp. v. Ionics, Inc.*, 53 USPQ2d, 1071, 1085 (D. Mass 1999), *quoting*, *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1366, 42 USPQ2d 1001 (Fed. Cir), *cert. denied*, 522 U.S. 963 (1977)). Appellants maintain the assertion that the suggestion in Komatsu of a metal silicide layer made of silicon and, to quote the Examiner, "one of many metals including ruthenium" (Office Action mailed 10 January 2006, page 6, item 8, lines 5-7) is simply a tossing out of the mere germ of an idea, and furnishes insufficient detail to provide an enabling disclosure that anticipates Appellants' invention.

Appellants additionally point out that in the final Office Action mailed 21 July 2006, which immediately precedes the present Appeal and which issued subsequent to the 10 January 2006 Office Action, the Examiner asserted that "[i]n column 22, lines 29-39, Komatsu bluntly states a metal silicide layer made of silicon and a metal such as ruthenium, and further states that CVD may be used in its formation. Such a disclosure is more than a 'germ' of an idea and clearly states the metal used and its method of making (even though the claims are directed towards product) in the formation of the metal silicide layer." (page 6, item 8, lines 6-10). Appellants earnestly disagree with this characterization of Komatsu, which was revised from the Examiner's previous characterization of Komatsu in the 10 January 2006 Office Action, wherein the Examiner stated that "Komastsu clearly discloses that the metal silicide layer may be made of

silicon and one of many metals including ruthenium."

First, Komatsu does not bluntly state "a metal silicide layer made of silicon and a metal such as ruthenium" as purported by the Examiner in the Office Action mailed 21 July 2006. Instead, Komatsu discloses that in place of the metal silicide layer made of WSi_x, there may be used a metal silicide layer "made of silicon and one of many metals including ruthenium" as contended by the Examiner in the previous Office Action mailed 10 January 2006. Thus, Appellants assert that the Examiner mischaracterized his own characterization of Komatsu to support his argument.

Further, the Examiner, in the Office Action mailed 21 July 2006 stated that Komatsu "clearly states the metal used and its method of making . . . in the formation of the metal silicide layer." Appellants respectfully point out that Komatsu discloses formation of a complex film including tungsten silicide (Komatsu, col. 4, lines 40-44) or formation of a metal silicide layer which may be tungsten silicide (Komatsu, col. 5, lines 44-45 and 56-65) or, alternatively, may include titanium silicide, tungsten silicide, molybdenum silicide, or tantalum silicide (Komatsu, col. 6, lines 1-2 and 19-22). In addition, working examples of Komatsu that disclose the use of specific metal silicide layers (e.g., Process 120 (col. 10, lines 35-39); Process 140 (col. 11, lines 1-7); Process 210 (col. 11, lines 24-27); Process 250 (col. 12, lines 6-8, 14-28, and 56-59; col. 13, lines 14-38); Process 340 (col. 16, lines 21-23 and col. 17, lines 56-57); Process 450 (col. 18, lines 57-62); Process 470 (col. 20, lines 8-10); Process 510 (col. 20, lines 22-31); and Process 540 (col. 21, lines 4-5 and 18-20) disclose tungsten silicide or titanium silicide, with the possiblility of substituting molybdenum silicide, titanium silicide, or tantalum silicide for tungsten silicide in Process 340 (col. 16, lines 21-23). Thus, any metal that Komatsu "clearly states" in the formation of a metal silicide layer would not include ruthenium. It is merely suggested at col. 22, lines 29-37, that in forming a contact hole, the tungsten silicide layer may be replaced by a metal silicide layer made of silicon and a metal such as titanium, molybdenum, tantalum, vanadium, chromium, cobalt, nickel, zirconium, niobium, rhodium, palladium, hafnium, platinum, manganese, iron, iridium, ruthenium, osmium, or rhenium.

Case law provides a test to assist in evaluating whether an invention is enabled. "The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation." *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) (*citing*, *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986). *See also*, M.P.E.P. §2164 (page 2100-186 to 187, Rev. 5, Aug. 2006). Factors to be considered when determining whether any necessary experimentation is "undue" include the following (the "Wands factors"):

(A) The breadth of the claims;
(B) The nature of the invention;
(C) The state of the prior art;
(D) The level of one of ordinary skill;
(E) The level of predictability in the art;
(F) The amount of direction provided by the inventor;
(G) The existence of working examples; and
(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988), *citing*, *Ex parte Forman*, 230 USPQ 546, 547 (Bd. Pat. App. & Int., 1986); M.P.E.P. §2164.01(a)(page 2100-187, Rev. 5, Aug. 2006). Appellants assert that Komatsu, taken as a whole and in view of the above factors, does not enable Appellants' claimed invention including a diffusion barrier layer formed of $RuSi_x$.

For example, as previously pointed out by Appellants, Komatsu specifically discloses in the Object and Summary of the Invention the provision of "tungsten silicide (WSi_x) formed by CVD" (e.g., col. 4, line 43; col. 4, line 58 to col. 5, line 6; col. 5, line 66 to col. 6, line 6; and col. 6, lines 19-22). In addition, the Summary also suggests that "the metal silicide layer may comprise titanium silicide, tungsten silicide, molybdenium silicide, or tantalum silicide" (col. 5 line 67 to col. 6, line 2, and col. 6, lines 19-22). Furthermore, of the seven exemplary process embodiments disclosed in the Detailed Description of the Preferred Embodiments, at col. 9, line 40 to col. 22, line 14, each of the embodiments that teach formation of a metal silicide layer

specifically teach a tungsten silicide layer (col. 8, lines 41-42; col. 10, lines 38-39; col. 11, lines 24-25; col. 17, line 57; col. 19, lines 24-25, and line 60; and col. 8-10 and lines 30-31) or a titanium silicide layer (col. 18, lines 57-61), as well as conditions for forming these layers. In addition, other specific silicides suggested for use in "forming a thin film or island-like region for a gate electrode may include a refractory metal silicide such as $MoSi_x$, $TiSi_x$, or $TaSi_x$" (col. 16, lines 21-23). Thus, Komatsu provides direction and working examples that might arguably provide enablement for deposition of tungsten silicide and titanium silicide layers. Komatsu may also arguably provide direction for use of $MoSi_x$, $TiSi_x$, or $TaSi_x$ for forming a thin film or island-like region. Appellants maintain their assertion, however, Komatsu fails to enable chemical vapor codeposition of a diffusion barrier layer formed of $RuSi_x$, an assertion that the Examiner has failed to counter with a showing of how a diffusion barrier layer formed of $RuSi_x$, is enabled, beyond the mere mention of using one of 19 proposed metals, one of which is ruthenium, to form a metal silicide which may be substituted for tungsten silicide.

Komatsu fails to clearly and unambiguously disclose a chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$, as recited in Appellants' claims. Komatsu merely suggests that "in place of the metal silicide layer made of WSi_x, there may be used a metal silicide layer made of silicon and a metal such as titanium (Ti), molybdenium (Mo), tantalum (Ta), vanadium (V), chromium (Cr), cobalt (Co), nickel (Ni), zirconium (Zr), niobium (Nb), rhodium (Rh), palladium (Pd), hafnium (Hf), platinum (Pt), manganese (Mn), iron (Fe), iridium (Ir), ruthenium (Ru), osmium (Os), or rhenium (Re)" (col. 22, lines 29-37). Even if Komatsu could arguably be interpreted as naming a ruthenium silicide layer based on the suggestion of a metal silicide layer made of silicon and any one of 19 possible metals, one of which is ruthenium, Appellants respectfully submit that the mere naming of the possibility of a ruthenium silicide layer by Komatsu fails to provide the enablement necessary for Komatsu to anticipate the present claims.

In addition, Komatsu suggests that a metal silicide layer may be formed by sputtering, deposition or CVD (col. 22, lines 32-39). Komatsu, however, neither suggests nor discloses

precursor compositions (e.g., ruthenium complexes and optional solvents), chemical vapor deposition systems, or conditions required for chemical vapor codeposition of a diffusion barrier layer formed of $RuSi_x$. Further, the Examiner has provided no evidence that chemical vapor codeposition of $RuSi_x$ or that ruthenium precursors for chemical vapor codeposition were known in the art at the time of the present invention. Appellants, therefore, submit that the Examiner has failed to present a convincing argument to show how Komatsu, at the time the present invention was made, would have enabled the skilled person to form a $RuSi_x$ diffusion barrier layer by chemical vapor codeposition.

Appellants assert, for at least the above reasons, that the disclosure of Komatsu, taken as a whole, does not enable the chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$ according to Appellants' claims. Thus, Appellants respectfully submit that Komatsu fails to anticipate present claims 45-48 and 54-59.

B. Claims 45, 46, 50, 51, 57-59, and 63-65 are not unpatentable under 35 U.S.C. §103(a) over Kuroiwa et al. (U.S. Patent No. 6,239,460 B1) in view of Agostinelli et al. (U.S. Patent No. 5,017,551)

1. Claims 45, 46, 50, 51, 57-59, and 63-65

In order to establish a *prima facie* case of obviousness, the Examiner must establish that there is a motivation to combine the documents (or modify the teachings of a document) to achieve the claimed invention, with a reasonable expectation of success. Further, the references must teach or suggest every element of the claimed invention. For at least the reasons set forth below, it is respectfully submitted that the Examiner has failed to make the requisite showing of a *prima facie* case of obviousness of claims 45, 46, 50, 51, 57-59, and 63-65 over Kuroiwa et al. in view of Agostinelli et al.

Appellants note the Examiner's admission that "Kuroiwa does not disclose at least one of the first and second electrode comprising a chemical vapor diffusion barrier layer" (Office Action issued 21 July 2006, page 3, item 4, lines 6-7). The Examiner further asserted that Agostinelli et al. disclose "a metal silicide layer made of ruthenium[,] . . . that various,

convenient methods can be used to form the metal silicide such as chemical vapor deposition procedures[, and that] . . . it would have been obvious to one of ordinary skill in the art at the time of invention to have at least one of the first and second electrode comprising a chemical vapor diffusion barrier layer in order to conveniently form a [*sic*] electrode with adequate conductive properties." (Office Action issued 21 July 2006, page 3, item 4, lines 7-13). While a chemical vapor deposited diffusion barrier layer in general may be suggested by the disclosure of Agostinelli et al., Appellants maintain their contention that Agostinelli et al fail to teach or suggest a chemical vapor codeposited diffusion barrier layer over at least a portion of a surface or an electrode, wherein the diffusion barrier layer is formed of $RuSi_x$, as recited in the claims rejected herein by the Examiner.

Agostinelli et al. teach a circuit element "comprised of a substrate and an electrically conductive layer on the substrate." (Agostinelli et al., abstract). "The electrically conductive layer is comprised of a crystalline rare earth alkaline earth copper oxide." (Agostinelli et al., abstract). "A barrier layer is interposed between the electrically conductive layer and the substrate. The barrier layer contains magnesium, a group IVA metal, or a platinum group metal, either in an elemental state or in the form of an oxide or silicide." (Agostinelli et al., abstract). The platinum group metal may include ruthenium (Agostinelli et al., col. 4, line 31). Appellants submit, however, that Agostinelli et al. fail to provide an enabling disclosure of a chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$.

The Examiner stated that "Agostinelli also discloses (see, for example, column 20, lines 11-16) that various, convenient methods can be used to form the metal silicide such as chemical vapor deposition procedures." (Office Action issued 21 July 2006, page 3, item 4, lines 8-10). Appellants respectfully submit that Agostinelli et al. fail to enable a chemical vapor codeposted diffusion barrier layer formed of $RuSi_x$, for reasons similar to those provided above in connection with Appellants' response to the rejection of the claims as anticipated by Komatsu. Appellants assert that, in view of the disclosure of Agostinelli et al. taken as a whole, neither a chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$, nor, for that matter, any

chemical vapor codeposited diffusion barrier layer are enabled.

For example, although Agostinelli et al. may suggest a ruthenium oxide barrier layer (e.g., "[t]he barrier layer contains a metal, in its elemental form, or in the form of an oxide or silicide, chosen from the group consisting of magnesium, a group IVA metal and a platinum group metal" (col. 4, lines 21-24), and "[t]he term 'platinum group metal' refers to a metal from the second and third triads of Group VIIIA of the periodic table – i.e., ruthenium, rhodium, or palladium forming the second triad or osmium, iridium, or platinum forming the third triad" (col. 4, lines 28-32)), this suggestion is simply a tossing out of the mere germ of an idea, and, in view of the entire teachings of Agostinelli et al., furnishes insufficient detail to provide an enabling disclosure of a chemical vapor codeposited ruthenium silicide barrier layer in accordance with Appellants' rejected claims. Furthermore, the Examiner provided no counterargument beyond bare assertion to support the premise that Agostinelli et al. provide an enabling disclosure of a ruthenium silicide layer.

The Examiner stated in the Office Action mailed 21 July 2006 that "Agostinelli clearly discloses (see, for example, column 4, lines 22-33) a ruthenium silicide layer by stating a metal in the form of silicide chosen from a platinum group metal which includes ruthenium. This is not a suggestion but a clear disclosure of a ruthenium silicide layer." (page 7, lines 1-5). Appellants strongly disagree. At column 4, lines 22-33, Agostinelli et al. recite that the barrier layer contains a metal, in its elemental form or in the form of an oxide or silicide (e.g., 3 alternative forms of a metal). Agostinelli et al. further recite that the metal is chosen from the group of magnesium, a Group IVA metal and a platinum group metal, with the Group IVA metal referring to titanium, zirconium, or hafnium, and the platinum group metal referring to ruthenium, rhodium, palladium, osmium, iridium, or platinum (e.g., 10 different metals). At best, Agostinelli et al. merely name ruthenium silicide as one among a group of 30 possible barrier layers indicated at column 4, lines 22-33 of Agostinelli et al. (10 different metals x 3 alternative forms of the metal = 30 possible barrier layers). However, Appellants respectfully submit that Agostinelli et al. fail to provide sufficient enablement for one of skill in the art to

make the presently claimed ruthenium silicide diffusion barrier layer.

For example, none of the working examples of Agostinelli et al. provide an enabling disclosure of a ruthenium silicide barrier layer. Examples 1-5 (col. 20, line 23 to col. 21, line 60) disclose the use of a ZrO_2 barrier layer deposited by thermal decomposition. Example 6 (col. 21, line 61 to col. 22, line 33) discloses the use of a titanium metal barrier layer formed by electron beam deposition. Example 7 (col. 2, lines 35-43) discloses the use of a barrier layer of a mixture of TiO and TiO_2 formed by electron beam deposition of titanium, then heat treatment of the elemental metal layer. Examples 8, 10, and 12 (col. 22, lines 45-50 and col. 22, line 63 to col. 23, line 12) disclose the use of a zirconium metal barrier layer provided by electron beam deposition, and Examples 9, 11, and 13 (col. 22, lines 52-61 and col. 22, line 63 to col. 23, line 12) disclose a barrier layer of a mixture of ZrO_2 and $ZrSi_2$ formed by first providing the elemental zirconium by electron beam deposition, then providing heat treatment. Example 14 (col. 23, lines 13-22) discloses a magnesium metal layer formed by vacuum vapor deposition, which is subsequently heated to form a barrier layer of Mg_2SiO_4 and MgO. Finally, Example 15 (col. 23, lines 23-31) discloses a platinum metal barrier layer provided by electron beam deposition. None of these working examples teach or suggest a ruthenium silicide barrier layer.

As pointed out above, there are no working examples of a barrier layer formed of ruthenium silicide. Of the fifteen examples provided by Agostinelli et al., only Examples 9, 11, and 13 disclose the provision of a metal silicide barrier layer. Furthermore, in each of these instances the barrier layer is a mixture of the metal silicide and the metal oxide formed by the provision of the elemental metal deposited on a silicon substrate and heated to 1000°C in oxygen. It is further pointed out that the exemplified metal silicides are zirconium silicide (Examples 9 and 11) and magnesium silicide, and also that none of the working examples use ruthenium of any form (e.g., elemental, oxide, or silicide) in the barrier layers.

Additionally, with respect to the formation of the barrier layer, Agostinelli et al. teach, at column 19, lines 24-28, that the barrier layers "can be formed starting with barrier precursors, barrier metal-ligand compounds, where the ligands are chosen in the same manner as described

in connection with RAC precursors" (e.g., coating the substrate with precursors including at least one thermally volatilizable ligand, then heating to remove the volatilizable ligand, col. 5, lines 5-22). Alternatively, "[a] preferred approach for forming elemental barrier layers is to deposit the metal on the substrate by conventional electron beam techniques," then "[i]n subsequent heating . . . the barrier metal can, if desired, be converted to the corresponding oxide or silicide" (col. 19, lines 49-55).

Thus, Agostinelli et al. provide a detailed description of the process for providing amorphous layers of the rare earth-alkaline earth-copper (RAC) compositions, which process (e.g., thermal decomposition) was specifically identified as useful for providing the barrier layer (col. 19, lines 24-28) and disclosed in the working examples (e.g., Example 1, col. 20, lines 24-29). Agostinelli et al. also provide direction, as well as working examples (e.g., Example 9, col. 22, lines 53-59), to form a barrier layer by depositing an elemental metal layer by conventional electron beam techniques and, subsequently, convert the elemental layer to the corresponding oxide or silicide. Appellants assert, however, that the brief suggestion provided at the end of the Description of Preferred Embodiments that "the barrier layer can alternatively be formed by any other convenient conventional preparation process" such as electron beam deposition techniques, thermal decomposition, sputtering, vacuum vapor deposition, and metal-organic chemical vapor deposition procedures (col 19, line 49 to col. 20, line 16), fails to provide direction to the skilled person, in view of the entire disclosure of Agostinelli et al., to enable a chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$.

Further, Agsotinelli et al. fail to provide any disclosure or suggestion of precursor compositions (e.g., including ruthenium complexes and optional solvents), vapor codeposition systems, and conditions required for the chemical vapor codeposition of a diffusion barrier layer formed of $RuSi_x$. In addition, the Examiner has provided no evidence that chemical vapor codeposition of $RuSi_x$ was known in the art at the time of the present invention, and, further, that ruthenium precursors for chemical vapor codeposition where known in the art at the time of the present invention. Thus, Appellants respectfully submit that the Examiner has failed to present a

convincing line of reasoning as to how Agostinelli et al., at the time the present invention was made, would have enabled one of skill in the art to form a $RuSi_x$ diffusion barrier layer by chemical vapor codeposition.

Notably, the Examiner has failed to counter Appellants' assertion with any argument in support of the contention that Agostinelli et al. enable the disclosure of a chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$.

In summary, Appellants point out that Agostinelli et al. states that "[i]t is the discovery of this invention that specifically selected metals as well as their oxides and silicides when interposed between a substrate . . . and the RAC layer enhances the electrical conduction properties of the RAC layer" (col. 18, lines 38-43). Appellants assert that, in view of the foregoing comments and considering the disclosure of Agostinelli et al. as a whole, not only are there no examples of forming a $RuSi_x$ barrier layer by chemical vapor codeposition, there also is no specific enablement for chemical vapor codeposition of <u>any</u> barrier layer. The Examiner asserted that, in view of Agostinelli et al., "it would have been obvious to one of ordinary skill in the art at the time of invention to have at least one of the first and second electrode comprising a chemical vapor diffusion barrier layer," (page 3, item 4, lines 10-12 of the Office Action mailed 21 July 2006). However, no evidence has been provided to show that the level of one of ordinary skill and/or the state and predictability of the art at the time of filing was such that at best the mere naming of a ruthenium silicide diffusion barrier layer by Agostinelli et al. could provide an enabling disclosure of a chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$, according to Applicants' claims. As this teaching is not enabled, Agostinelli et al. fail to provide that which is missing from Kuroiwa.

<u>2. Claims 58-59 and 64-65</u>

With respect to dependent claims 58-59 and 64-65, the Examiner asserted that "Kuroiwa discloses the ruthenium silicide layer within an opening of the insulating film 110" (at page 4, lines 1-2 of the Office Action, mailed 21 July 2006). Appellants disagree, respectfully pointing

out that claims 58-59 and 64-65 recite a structure "wherein the diffusion barrier layer comprises a conformal layer within the opening" (claims 58 and 64) wherein the layer may be of uniform thickness (claims 59 and 65). Kuroiwa et al., on the other hand, teach a plug 111 in the contact hole 110a wherein the plug 111 may be silicon or a metal, and "the metal electrode 130 is, as shown in FIG. 6, *deposited on the top surface of the of the plug 111 and the surface of the first interlayer insulating film 110.*" (Kuroiwa et al., col. 12, lines 26-28, emphasis added). Thus, Kuroiwa et al. fail to teach or suggest a diffusion barrier layer including a conformal layer within the opening according to Applicants' claims 58-59 and 64-65. Furthermore, Agostinelli et al. fail to teach or suggest the openings according to Appellicants' claims. Thus, claims 58-59 and 64-65 are nonobvious over the combination of Kuroiwa et al. and Agostinelli et al.

Thus, for at least the above reasons, Applicants assert that independent claims 45, 50, 57, and 63, and dependent claims 46, 51, 58-59 and 64-65 are nonobvious over the combination of Kuroiwa et al. and Agostinelli et al.

C. Claims 48, 49, 54, 55, and 69-74 are not unpatentable under 35 U.S.C. § 103(a) over Kuroiwa et al. (U.S. Patent No. 6,239,460 B1) in view of Agostinelli et al. (U.S. Patent No. 5,017,551) as applied to claims 45, 46, 50, 51, 57-59, and 63-65, and further in view of Lee et al. (U.S. Patent No. 5,872,041)

1. Claims 48, 49, 54, 55, and 69-74

The Examiner rejected claims 48, 49, 54, 55 and 69-74 under 35 U.S.C. §103(a) as being unpatentable over Kuroiwa et al. (U.S. Patent No. 6,239,460) in view of Agostinelli et al. (U.S. Patent No. 5,017,551) as applied to claims 45, 46, 50, 51, 57-59, and 63-65, and further in view of Lee et al. (U.S. Patent No. 5,872,041, hereinafter "Lee '041")). Appellants respectfully disagree.

Appellants respectfully submit that the cited documents do not teach or suggest all of the language recited in the present claims. Specifically, the combination of Kuroiwa et al. and Agostinelli et al., which has been discussed hereinabove, lacks, among other things, a chemical vapor codeposited $RuSi_x$ diffusion barrier layer. Appellants respectfully submit that Lee '041,

which "relates to a method for fabricating the electrodes of a semiconductor capacitor" (col. 1, lines 8-9), do not teach or suggest a $RuSi_x$ diffusion barrier layer, nor has the Examiner provided any support for any assertion that Lee '041 teach or suggest a $RuSi_x$ diffusion barrier layer. Thus, Lee '041 fail to cure the deficiencies of the combination of Kuroiwa et al. and Agostinelli et al.

2. Claims 69-74

With respect to claims 69-74, Appellants note that the Examiner stated that "Kuroiwa in view of Agostinelli does not disclose a silicon containing region" (page 4, item 5, lines 3-4 of the Office Action, mailed 21 July 2006). Applicants do not understand this statement, as Kuroiwa et al. clearly disclose the deposition of ruthenium on a silicon containing surface (e.g., column 10, lines 48-49, reciting that "plug 111 was made of polycrystal silicon containing doped phosphorus"). Further, Kuroiwa et al. disclose that the deposition of ruthenium is followed by heat treatment to form a ruthenium silicide layer through a salicidation process. Thus, a silicon containing surface is not only disclosed by Kuroiwa et al.; Kuroiwa's disclosed *salicidation process* to form a ruthenium silicide layer actually *requires* a silicon containing surface.

In contrast, claims 69-74 recite that "the surface defining the opening is not a silicon containing surface." In view of the remarks presented herein above, Appellants respectfully submit that any suggestion by the Examiner to modify the teachings of Kuroiwa et al. in view of Agostinelli et al. to form a ruthenium silicide layer on a surface defining an opening that is not a silicon containing surface would impermissibly render the teaching of Kuroiwa et al. inoperative. *See, for example*, M.P.E.P. 2143.01 (page 2100-127 through 130, Rev. 5, Aug. 2006), which states that "[i]f proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification."

For at least the foregoing reasons, Appellants respectfully submit that claims 48, 49, 54, 55, and 69-74 are not *prima facie* obvious under 35 U.S.C. §103 over Kuroiwa et al. in view of

Agostinelli et al., and further in view of Lee '041.

D. Claims 52 and 53 are not unpatentable under 35 U.S.C. § 103(a) over Kuroiwa et al. (U.S. Patent No. 6,239,460 B1) in view of Agostinelli et al. (U.S. Patent No. 5,017,551) in view of Lee et al. (U.S. Patent No. 5,872,041) as applied to claims 48, 49, 54, 55, and 69-74, and further in view of Matsubara et al. (U.S. Patent No. 5,122,923)

Specifically, in the present case, the deficiencies of Kuroiwa et al. in view of Agostinelli et al. and further in view of Lee et al. '041 have been discussed hereinabove. In brief, none of Kuroiwa et al., Agostinelli et al., and/or Lee '041 disclose or suggest a chemical vapor codeposited $RuSi_x$ diffusion barrier layer. Moreover, Appellants respectfully submit that Matsubara et al., also fail to disclose or suggest a chemical vapor codeposited $RuSi_x$ diffusion barrier layer. Thus, Applicants respectfully submit that claims 52 and 53 are patentable over Kuroiwa et al. in view of Lee et al. '041, and further in view of Matsubara et al.

Applicants note that the Examiner stated that "Kuroiwa in view of Agostinelli in view of Lee does not disclose the first electrode comprising one or more additional conductive layers. However it was well known in the art at the time of invention to use multiple layers in the electrodes of a capacitor" and that "Matsubara discloses a lower electrode comprising multiple layers of ruthenium, ruthenium oxide, ruthenium silicide and stacked structures consisting of these materials. It would have been obvious to one of ordinary skill in the art at the time of invention to have the first electrode comprising one or more additional conductive layers in order to form an adequate bottom electrode, and since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art." (Office Action, mailed 21 July 2006, page 5, item 6, lines 4-12).

It is unclear how the disclosure in Matsubara et al. regarding "[l]ayers of ruthenium, ruthenium oxide, ruthenium silicide and stacked structures consisting of these materials" (col. 4, lines 25-27) in connection with the Examiner's foregoing statements would suggest to one skilled in the art Appellants' capacitor structure according to claims 52 and 53, wherein "the first

electrode comprises a diffusion barrier layer, wherein the diffusion barrier layer of the first electrode is formed on at least a portion of a silicon containing region, and further wherein the first electrode comprises one or more additional conductive layers formed over the diffusion barrier layer, the one or more additional conductive layers formed of at least one of a metal and a conductive metal oxide." Furthermore, the Examiner has provided no reasoning in support of such suggestion. Nonetheless, the combination of Kuroiwa et al., Agostinelli et al., Lee '041, and Matsubara et al. still fail to teach a chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$, as recited in Appellants' claim 52.

In order to establish a *prima facie* case of obviousness, the references must teach or suggest all the claim limitations. *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 at 93 ("Focusing on the obviousness of substitutions and differences instead of on the invention as a whole, . . . was a legally improper way to simplify the difficult determination of obviousness."). One cannot "simply [to] engage in a hindsight reconstruction of the claimed invention, using the Applicant's structure as a template and selecting elements from references to fill the gaps." *In re Gorman*, 933 F2d 982, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). Further, both the suggestion for combining the teachings of the prior art to make the invention and the reasonable likelihood of its success must be founded in the prior art and not in the teachings of Applicants' disclosure. *In re Dow Chem.*, 837 F.2d 469, 473, 5 U.S.P.Q.2d 1529, 1531 (Fed. Cir. 1988). Here, the cited art neither suggests the combination of its teachings nor suggests the reasonable likelihood that such a combination would result in the present invention.

Furthermore, as recently reasserted in *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.* (411 F.3d 1332, 75 USPQ2d 1051 (Fed. Cir. 2005)), 35 U.S.C. §103 specifically requires an assessment of the claimed invention "as a whole." This "as a whole" assessment of the invention requires a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements from the cited references and combined them in the claimed manner. In other words, 35 U.S.C. §103 requires some suggestion or

motivation, before the invention itself, to make the new combination. *See*, *In re Rouffet*, 149 F.3d 1350, 1355-56, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998).

This "as a whole" instruction in 35 U.S. §103 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might successfully break an invention into its component parts, then find a reference corresponding to each component. This line of reasoning would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. Further, this improper method would discount the value of combining various existing features or principles in a new way to achieve a new result - often the essence of invention. *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275, 69 USPQ2d 1686, 1690 (Fed. Cir. 2004). Simply identifying the various elements of a claim in the cited references does not render a claim obvious. *Ruiz*, 357 F.3d at 1275. Instead, 35 U.S. §103 requires some suggestion or motivation in the prior art to make the new combination. *Rouffet*, 149 F.3d at 1355-56. Appellants submit that the Examiner has engaged in an improper part by part analysis of the claimed invention.

For at least the foregoing reasons, Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness of claims 52 and 53 over Kuroiwa et al. in view of Agostinelli et al., in view of Lee '041, and further in view of Matsubara et al.

E. Claims 60-62 and 66-68 are not unpatentable under 35 U.S.C. § 103(a) over Kuroiwa et al. (U.S. Patent No. 6,239,460 B1) in view of Agostinelli et al. (U.S. Patent No. 5,017,551) as applied to claims 45, 46, 50, 51, 57-59, and 63-65, and further in view of Lee et al. (U.S. Patent No. 5,897,350)

The deficiencies of Kuroiwa et al. in view of Agostinelli et al. have been discussed hereinabove. Neither Kuroiwa et al. nor Agostinelli et al. disclose or suggest a chemical vapor codeposited $RuSi_x$ diffusion barrier layer. Additionally, Lee et al. (U.S. Patent No. 5,897,350, hereinafter "Lee '350"), which "relates to a memory cell structure of of [*sic*] semiconductor memory device" (col. 1, lines 6-7), also fail to disclose or suggest a chemical vapor codeposited $RuSi_x$ diffusion barrier layer, recited in independent claims 60 and 66. Further, Appellants note

that the Examiner has provided no counterargument to Appellants' assertion concerning Lee '350.

Thus, for at least the above reasons, Appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness of claims 60 and 66 under 35 U.S.C. §103 over Kuroiwa et al. in view of Agostinelli et al., and further in view of Lee '350.

VIII. SUMMARY

For the foregoing reasons, Appellants respectfully request that the Board review and reverse the rejection of claims 45-74 as discussed herein, and that notification of the allowance of these claims be issued.

Respectfully submitted
By
Mueting, Raasch & Gebhardt, P.A.
P.O. Box 581415
Minneapolis, MN 55458-1415
(612)305-1220

Date: December 18, 2006

By: _____
Loren D. Albin
Reg. No. 37,763
Direct Dial: (612)305-1225

CERTIFICATE UNDER 37 CFR §1.10:
"Express Mail" mailing label number: EV 201878625 US Date of Deposit: December 18, 2006
The undersigned hereby certifies that this paper is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR §1.10 on the date indicated above and is addressed to **Mail Stop Appeal Brief- Patents**, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

By: _____
Name: Deb Schurmann

The pending claims are provided below.

1.-44. (Canceled)

45. (Rejected) A semiconductor device structure, the structure comprising:

a substrate assembly including a surface; and

a chemical vapor codeposited diffusion barrier layer over at least a portion of the surface, wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10.

46. (Rejected) The structure of claim 45, wherein x is in the range of about 1 to about 3.

47. (Rejected) The structure of claim 46, wherein x is about 2.0.

48. (Rejected) The structure of claim 45, wherein the at least a portion of the surface is a silicon containing surface and further wherein the structure includes one or more additional conductive layers over the diffusion barrier layer formed of at least one of a metal and a conductive metal oxide.

49. (Rejected) A semiconductor device structure, the structure comprising:

a substrate assembly including a surface, wherein the at least a portion of the surface is a silicon containing surface; and

a chemical vapor codeposited diffusion barrier layer over at least a portion of the surface,

wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10,

wherein the structure includes one or more additional conductive layers over the diffusion barrier layer formed of at least one of a metal and a conductive metal oxide, and

further wherein the one or more conductive layers are formed from materials selected from the group of RuO_2, RhO_2, MoO_2, IrO_2, Ru, Rh, Pd, Pt, and Ir.

50. (Rejected) A capacitor structure comprising:

a first electrode;

a high dielectric material on at least a portion of the first electrode; and

a second electrode on the dielectric material, wherein at least one of the first and second electrode comprises a chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$, where x is in the range of about 0.01 to about 10.

51. (Rejected) The structure of claim 50, wherein x is in the range of about 1 to about 3.

52. (Rejected) A capacitor structure comprising:

a first electrode;

a high dielectric material on at least a portion of the first electrode; and

a second electrode on the dielectric material, wherein at least one of the first and second electrode comprises a chemical vapor codeposited diffusion barrier layer formed of $RuSi_x$, where x is

in the range of about 0.01 to about 10,

wherein the first electrode comprises a diffusion barrier layer, wherein the diffusion barrier layer of the first electrode is formed on at least a portion of a silicon containing region, and further wherein the first electrode comprises one or more additional conductive layers formed over the diffusion barrier layer, the one or more additional conductive layers formed of at least one of a metal and a conductive metal oxide.

53. (Rejected) The structure of claim 52, wherein the one or more additional conductive layers are formed from materials selected from the group of RuO_2, RhO_2, MoO_2, IrO_2, Ru, Pt, and Ir.

54. (Rejected) An integrated circuit structure comprising:

a substrate assembly including at least one active device and a silicon containing region; and

an interconnect formed relative to the at least one active device and the silicon containing region, the interconnect including a chemical vapor codeposited diffusion barrier layer on at least a portion of the silicon containing region, wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10.

55. (Rejected) The structure of claim 54, wherein x is in the range of about 1 to about 3.

56. (Rejected) The structure of claim 54, further comprising a conductive contact material formed relative to the diffusion barrier layer.

57. (Rejected) A semiconductor device structure, the structure comprising:

a substrate assembly including a surface defining an opening having an aspect ratio greater than about 1; and

a chemical vapor codeposited diffusion barrier layer on at least a portion of the surface defining the opening, wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10.

58. (Rejected) The structure of claim 57, wherein the diffusion barrier layer comprises a conformal layer within the opening.

59. (Rejected) The structure of claim 57, wherein the diffusion barrier layer comprises a conformal layer of uniform thickness within the opening.

60. (Rejected) A semiconductor device structure, the structure comprising:

a substrate assembly including a surface defining an opening having an aspect ratio greater than about 3; and

a chemical vapor codeposited diffusion barrier layer on at least a portion of the surface defining the opening, wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10.

61. (Rejected) The structure of claim 60, wherein the diffusion barrier layer comprises a conformal layer within the opening.

62. (Rejected) The structure of claim 60, wherein the diffusion barrier layer comprises a conformal layer of uniform thickness within the opening.

63. (Rejected) A capacitor structure comprising:

a first electrode;

a high dielectric material on at least a portion of the first electrode; and

a second electrode on the dielectric material, wherein at least one of the first and second electrodes has a surface defining an opening having an aspect ratio greater than about 1, wherein a chemical vapor codeposited diffusion barrier layer is on at least a portion of the surface defining the opening, and wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10.

64. (Rejected) The capacitor structure of claim 63, wherein the diffusion barrier layer comprises a conformal layer within the opening.

65. (Rejected) The capacitor structure of claim 63, wherein the diffusion barrier layer comprises a conformal layer of uniform thickness within the opening.

66. (Rejected) A capacitor structure comprising:

a first electrode;

a high dielectric material on at least a portion of the first electrode; and

a second electrode on the dielectric material, wherein at least one of the first and second electrodes has a surface defining an opening having an aspect ratio greater than about 3, wherein a chemical vapor codeposited diffusion barrier layer is on at least a portion of the surface defining the opening, and wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10.

67. (Rejected) The capacitor structure of claim 66, wherein the diffusion barrier layer comprises a conformal layer within the opening.

68. (Rejected) The capacitor structure of claim 66, wherein the diffusion barrier layer comprises a conformal layer of uniform thickness within the opening.

69. (Rejected) A semiconductor device structure, the structure comprising:

a substrate assembly including a surface defining an opening, with the proviso that the surface defining the opening is not a silicon containing surface; and

a chemical vapor codeposited diffusion barrier layer on at least a portion of the surface defining the opening, wherein the diffusion barrier layer is formed of $RuSi_x$, where x is in the range of about 0.01 to about 10.

70. (Rejected) The structure of claim 69, wherein the diffusion barrier layer comprises a conformal layer within the opening.

71. (Rejected) The structure of claim 69, wherein the diffusion barrier layer comprises a conformal layer of uniform thickness within the opening.

72. (Rejected) The structure of claim 69, wherein the opening has an aspect ratio greater than about 1.

73. (Rejected) The structure of claim 72, wherein the diffusion barrier layer comprises a conformal layer within the opening.

74. (Rejected) The structure of claim 72, wherein the diffusion barrier layer comprises a conformal layer of uniform thickness within the opening.

EVIDENCE APPENDIX
Serial No. 09/603,132
Docket No. 150.00650102

U.S. Patent No. 5,907,789; issued May 25, 1999 to Komatsu. First cited by the Examiner in the Office Action mailed July 26, 2005.

U.S. Patent No. 6,239,460 B1; issued May 29, 2001 to Kuroiwa et al. First cited by the Examiner in the Office Action mailed June 18, 2002.

U.S. Patent No. 5,017,551; issued May 21, 1991 to Agostinelli et al. First cited by the Examiner in the Office Action mailed July 26, 2005.

U.S. Patent No. 5,872,041; issued February 16, 1999 to Lee et al. First cited by the Examiner in the Office Action mailed July 26, 2005.

U.S. Patent No. 5,122,923; issued June 16, 1992 to Matsubara et al. First cited by the Examiner in the Office Action mailed April 10, 2001.

U.S. Patent No. 5,897,350; issued April 27, 1999 to Lee et al. First cited by the Examiner in the Office Action mailed July 26, 2005.

RELATED PROCEEDINGS APPENDIX

Serial No. 09/603,132

Docket No. 150.00650102

None.

CITED AUTHORITIES AND DOCUMENTS APPENDIX

Serial No. 09/603,132

Docket No. 150.00650102

M.P.E.P. §2143.01
M.P.E.P. §2121.01
M.P.E.P. §2164
M.P.E.P. §2164.01(a)

In re Hoeksema, 399 F.2d 269, 158 USPQ 596 (CCPA 1968).

Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education and Research, 346 F.3d 1051, 68 USPQ2d 1373 (Fed. Cir. 2003).

In re Donohue, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

Paperless Accounting, Inc. v. Bay Area Rapid Transit System, 804 F.2d 659, 231 USPQ 649, (Fed. Cir. 1986).

United States Filter Corp. v. Ionics, Inc., 68 FSupp.2d 48, 53 USPQ2d, 1071 (D. Mass 1999).

Genentech, Inc. v. Novo Nordisk A/S, 108 F.3d 1361, 42 USPQ2d 1001 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 963 (1997).

United States v. Telectronics, Inc., 857 F.2d 778, 8 USPQ2d 1217 (Fed. Cir. 1988).

In re Wands, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988).

Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986).

In re Gorman, 933 F2d 982, 18 U.S.P.Q.2d 1885 (Fed. Cir. 1991).

In re Dow Chem., 837 F.2d 469, 5 U.S.P.Q.2d 1529 (Fed. Cir. 1988).

Princeton Biochemicals, Inc. v. Beckman Coulter, Inc., 411 F.3d 1332, 75 USPQ2d 1051 (Fed. Cir. 2005).

In re Rouffet, 149 F.3d 1350, 47 USPQ2d 1453 (Fed. Cir. 1998).

Ruiz v. A.B. Chance Co., 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004).

2143.01 Suggestion or Motivation To Modify the References [R-5]

I. THE PRIOR ART MUST SUGGEST THE DESIRABILITY OF THE CLAIMED INVENTION

"There are three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art." *In re Rouffet,* 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998) (The combination of the references taught every element of the claimed invention, however without a motivation to combine, a rejection based on a *prima facie* case of obvious was held improper.). The level of skill in the art cannot be relied upon to provide the suggestion to combine references. *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999).

"In determining the propriety of the Patent Office case for obviousness in the first instance, it is necessary to ascertain whether or not the reference teachings would appear to be sufficient for one of ordinary skill in the relevant art having the reference before him to make the proposed substitution, combination, or other modification." *In re Linter*, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so >. *In re Kahn*, 441 F.3d 977, 986, 78 USPQ2d 1329, 1335 (Fed. Cir. 2006) (discussing rationale underlying the motivation-suggestion-teaching requirement as a guard against using hindsight in an obviousness analysis). The teaching, suggestion, or motivation must be< found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. "The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art." *In re Kotzab,* 217 F.3d 1365, 1370, 55 USPQ2d 1313, 1317 (Fed. Cir. 2000). See also *In re Lee,* 277 F.3d 1338, 1342-44, 61 USPQ2d 1430, 1433-34 (Fed. Cir. 2002) (discussing the importance of relying on objective evidence and making specific factual findings with respect to the motivation to combine references); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988); *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992).

In *In re Fulton*, 391 F.3d 1195, 73 USPQ2d 1141 (Fed. Cir. 2004), the claims of a utility patent application were directed to a shoe sole with increased traction having hexagonal projections in a "facing orientation." 391 F.3d at 1196-97, 73 USPQ2d at 1142. The Board combined a design patent having hexagonal projections in a facing orientation with a utility patent having other limitations of the independent claim. 391 F.3d at 1199, 73 USPQ2d at 1144. Applicant argued that the combination was improper because (1) the prior art did not suggest having the hexagonal projections in a facing (as opposed to a "pointing") orientation was the "most desirable" configuration for the projections, and (2) the prior art "taught away" by showing desirability of the "pointing orientation." 391 F.3d at 1200-01, 73 USPQ2d at 1145-46. The court stated that "the prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *Id.* The court emphasized that the proper inquiry is "'whether there is something in the prior art as a whole to suggest the *desirability*, and thus the obviousness, of making the combination,' not whether there is something in the prior art as a whole to suggest that the combination is the most desirable combination available." *Id.* In affirming the Board's obviousness rejection, the court held that the prior art as a whole suggested the desirability of the combination of shoe sole limitations claimed, thus providing a motivation to combine, which need not be supported by a finding that the prior art suggested that the combination claimed by the applicant was the preferred, or most desirable combination over the other alternatives. *Id.*

In *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 69 USPQ2d 1686 (Fed. Cir. 2004), the patent claimed underpinning a slumping building foundation using a screw anchor attached to the foundation by a metal bracket. One prior art reference taught a screw anchor with a concrete bracket, and a second prior art reference disclosed a pier anchor with a metal bracket. The court found motivation to combine the references to

arrive at the claimed invention in the "nature of the problem to be solved" because each reference was directed "to precisely the same problem of underpinning slumping foundations." *Id.* at 1276, 69 USPQ2d at 1690. The court also *rejected* the notion that "an express written motivation to combine must appear in prior art references...." *Id.* at 1276, 69 USPQ2d at 1690.

In *In re Kotzab*, the claims were drawn to an injection molding method using a single temperature sensor to control a plurality of flow control valves. The primary reference disclosed a multizone device having multiple sensors, each of which controlled an associated flow control valve, and also taught that one *system* may be used to control a number of valves. The court found that there was insufficient evidence to show that one *system* was the same as one *sensor*. While the control of multiple valves by a single sensor rather than by multiple sensors was a "technologically simple concept," there was no finding "as to the specific understanding or principle within the knowledge of the skilled artisan" that would have provided the motivation to use a single sensor as the system to control more than one valve. 217 F.3d at 1371, 55 USPQ2d at 1318.

In *In re Fine*, the claims were directed to a system for detecting and measuring minute quantities on nitrogen compounds comprising a gas chromatograph, a converter which converts nitrogen compounds into nitric oxide by combustion, and a nitric oxide detector. The primary reference disclosed a system for monitoring sulfur compounds comprising a chromatograph, combustion means, and a detector, and the secondary reference taught nitric oxide detectors. The examiner and Board asserted that it would have been within the skill of the art to substitute one type of detector for another in the system of the primary reference, however the court found there was no support or explanation of this conclusion and reversed.

In *In re Jones*, the claimed invention was the 2-(2¢-aminoethoxy) ethanol salt of dicamba, a compound with herbicidal activity. The primary reference disclosed *inter alia* the substituted ammonium salts of dicamba as herbicides, however the reference did not specifically teach the claimed salt. Secondary references teaching the amine portion of the salt were directed to shampoo additives and a byproduct of the production of morpholine. The court found there was no suggestion to combine these references to arrive at the claimed invention.

II. WHERE THE TEACHINGS OF THE PRIOR ART CONFLICT, THE EXAMINER MUST WEIGH THE SUGGESTIVE POWER OF EACH REFERENCE

The test for obviousness is what the combined teachings of the references would have suggested to one of ordinary skill in the art, and all teachings in the prior art must be considered to the extent that they are in analogous arts. Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. *In re Young*, 927 F.2d 588, 18 USPQ2d 1089 (Fed. Cir. 1991) (Prior art patent to Carlisle disclosed controlling and minimizing bubble oscillation for chemical explosives used in marine seismic exploration by spacing seismic sources close enough to allow the bubbles to intersect before reaching their maximum radius so the secondary pressure pulse was reduced. An article published several years later by Knudsen opined that the Carlisle technique does not yield appreciable improvement in bubble oscillation suppression. However, the article did not test the Carlisle technique under comparable conditions because Knudsen did not use Carlisle's spacing or seismic source. Furthermore, where the Knudsen model most closely approximated the patent technique there was a 30% reduction of the secondary pressure pulse. On these facts, the court found that the Knudsen article would not have deterred one of ordinary skill in the art from using the Carlisle patent teachings.).

III. FACT THAT REFERENCES CAN BE COMBINED OR MODIFIED IS NOT SUFFICIENT TO ESTABLISH *PRIMA FACIE* OBVIOUSNESS

The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir. 1990) (Claims were directed to an apparatus for producing an aerated cementitious composition by drawing air into the

cementitious composition by driving the output pump at a capacity greater than the feed rate. The prior art reference taught that the feed means can be run at a variable speed, however the court found that this does not require that the output pump be run at the claimed speed so that air is drawn into the mixing chamber and is entrained in the ingredients during operation. Although a prior art device "may be capable of being modified to run the way the apparatus is claimed, there must be a suggestion or motivation in the reference to do so." 916 F.2d at 682, 16 USPQ2d at 1432.). See also *In re Fritch*, 972 F.2d 1260, 23 USPQ2d 1780 (Fed. Cir. 1992) (flexible landscape edging device which is conformable to a ground surface of varying slope not suggested by combination of prior art references).

IV. FACT THAT THE CLAIMED INVENTION IS WITHIN THE CAPABILITIES OF ONE OF ORDINARY SKILL IN THE ART IS NOT SUFFICIENT BY ITSELF TO ESTABLISH *PRIMA FACIE* OBVIOUSNESS

A statement that modifications of the prior art to meet the claimed invention would have been "'well within the ordinary skill of the art at the time the claimed invention was made'" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000) (Court reversed obviousness rejection involving technologically simple concept because there was no finding as to the principle or specific understanding within the knowledge of a skilled artisan that would have motivated the skilled artisan to make the claimed invention); *Al-Site Corp. v. VSI Int'l Inc.*, 174 F.3d 1308, 50 USPQ2d 1161 (Fed. Cir. 1999) (The level of skill in the art cannot be relied upon to provide the suggestion to combine references.).

V. THE PROPOSED MODIFICATION CANNOT RENDER THE PRIOR ART UNSATISFACTORY FOR ITS INTENDED PURPOSE

If proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) (Claimed device was a blood filter assembly for use during medical procedures wherein both the inlet and outlet for the blood were located at the bottom end of the filter assembly, and wherein a gas vent was present at the top of the filter assembly. The prior art reference taught a liquid strainer for removing dirt and water from gasoline and other light oils wherein the inlet and outlet were at the top of the device, and wherein a pet-cock (stopcock) was located at the bottom of the device for periodically removing the collected dirt and water. The reference further taught that the separation is assisted by gravity. The Board concluded the claims were *prima facie* obvious, reasoning that it would have been obvious to turn the reference device upside down. The court reversed, finding that if the prior art device was turned upside down it would be inoperable for its intended purpose because the gasoline to be filtered would be trapped at the top, the water and heavier oils sought to be separated would flow out of the outlet instead of the purified gasoline, and the screen would become clogged.).

"Although statements limiting the function or capability of a prior art device require fair consideration, simplicity of the prior art is rarely a characteristic that weighs against obviousness of a more complicated device with added function." *In re Dance*, 160 F.3d 1339, 1344, 48 USPQ2d 1635, 1638 (Fed. Cir. 1998) (Court held that claimed catheter for removing obstruction in blood vessels would have been obvious in view of a first reference which taught all of the claimed elements except for a "means for recovering fluid and debris" in combination with a second reference describing a catheter including that means. The court agreed that the first reference, which stressed simplicity of structure and taught emulsification of the debris, did not teach away from the addition of a channel for the recovery of the debris.).

VI. THE PROPOSED MODIFICATION CANNOT CHANGE THE PRINCIPLE OF OPERATION OF A REFERENCE

If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie* obvious. *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959) (Claims were directed to an oil seal comprising a bore engaging portion with outwardly biased resilient spring fingers inserted in a resilient sealing member. The primary reference relied upon in a rejection based on a combination of references disclosed an oil seal wherein the bore engaging portion was reinforced by a cylindrical sheet metal casing. Patentee taught the device required rigidity for operation, whereas the claimed invention required resiliency. The court reversed the rejection holding the "suggested combination of references would require a substantial reconstruction and redesign of the elements shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate." 270 F.2d at 813, 123 USPQ at 352.).

2143.02 Reasonable Expectation of Success Is Required

OBVIOUSNESS REQUIRES ONLY A REASONABLE EXPECTATION OF SUCCESS

The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (Claims directed to a method of treating depression with amitriptyline (or nontoxic salts thereof) were rejected as *prima facie* obvious over prior art disclosures that amitriptyline is a compound known to possess psychotropic properties and that imipramine is a structurally similar psychotropic compound known to possess antidepressive properties, in view of prior art suggesting the aforementioned compounds would be expected to have similar activity because the structural difference between the compounds involves a known bioisosteric replacement and because a research paper comparing the pharmacological properties of these two compounds suggested clinical testing of amitriptyline as an antidepressant. The court sustained the rejection, finding that the teachings of the prior art provide a sufficient basis for a reasonable expectation of success.); *Ex parte Blanc*, 13 USPQ2d 1383 (Bd. Pat. App. & Inter. 1989) (Claims were directed to a process of sterilizing a polyolefinic composition with high-energy radiation in the presence of a phenolic polyester antioxidant to inhibit discoloration or degradation of the polyolefin. Appellant argued that it is unpredictable whether a particular antioxidant will solve the problem of discoloration or degradation. However, the Board found that because the prior art taught that appellant's preferred antioxidant is very efficient and provides better results compared with other prior art antioxidants, there would have been a reasonable expectation of success.).

AT LEAST SOME DEGREE OF PREDICTABILITY IS REQUIRED; APPLICANTS MAY PRESENT EVIDENCE SHOWING THERE WAS NO REASONABLE EXPECTATION OF SUCCESS

Obviousness does not require absolute predictability, however, at least some degree of predictability is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 531 F.2d 1048, 189 USPQ 143 (CCPA 1976) (Claims directed to a method for the commercial scale production of polyesters in the presence of a solvent at superatmospheric pressure were rejected as obvious over a reference which taught the claimed method at atmospheric pressure in view of a reference which taught the claimed process except for the presence of a solvent. The court reversed, finding there was no reasonable expectation that a process combining the prior art steps could be successfully scaled up in view of unchallenged evidence showing that the prior art processes individually could not be commercially scaled up successfully.). See also *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1207-08, 18 USPQ2d 1016, 1022-23 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991) (In the context of a biotechnology case, testimony supported the conclusion that the references did not show that there was a reasonable expectation of success.); *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (The court held the claimed method would have been obvious

nonobvious material to obtain another novel, nonobvious material was claimed. The process was held obvious because the reduction reaction was old.); *In re Kanter*, 399 F.2d 249, 158 USPQ 331 (CCPA 1968) (Process of siliconizing a patentable base material to obtain a patentable product was claimed. Rejection based on prior art teaching the siliconizing process as applied to a different base material was upheld.); Cf. *In re Pleuddemann*, 910 F.2d 823, 15 USPQ2d 1738 (Fed. Cir. 1990) (Methods of bonding polymer and filler using a novel silane coupling agent held patentable even though methods of bonding using other silane coupling agents were well known because the process could not be conducted without the new agent); *In re Kuehl*, 475 F.2d 658, 177 USPQ 250 (CCPA 1973) (Process of cracking hydrocarbons using novel zeolite catalyst found to be patentable even though catalytic cracking process was old. "The test under 103 is whether in view of the prior art the invention as a whole would have been obvious at the time it was made, and the prior art here does not include the zeolite, ZK-22. The obviousness of the process of cracking hydrocarbons with ZK-22 as a catalyst must be determined without reference to knowledge of ZK-22 and its properties." 475 F.2d at 664-665, 177 USPQ at 255.); and *In re Mancy*, 499 F.2d 1289, 182 USPQ 303 (CCPA 1974) (Claim to a process for the production of a known antibiotic by cultivating a novel, unobvious microorganism was found to be patentable.).

2121 Prior Art; General Level of Operability Required to Make a *Prima Facie* Case

PRIOR ART IS PRESUMED TO BE OPERABLE/ ENABLING

When the reference relied on expressly anticipates or makes obvious all of the elements of the claimed invention, the reference is presumed to be operable. Once such a reference is found, the burden is on applicant to provide facts rebutting the presumption of operability. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). See also MPEP § 716.07.

WHAT CONSTITUTES AN "ENABLING DISCLOSURE" DOES NOT DEPEND ON THE TYPE OF PRIOR ART THE DISCLOSURE IS CONTAINED IN

The level of disclosure required within a reference to make it an "enabling disclosure" is the same no matter what type of prior art is at issue. It does not matter whether the prior art reference is a U.S. patent, foreign patent, a printed publication or other. There is no basis in the statute (35 U.S.C. 102 or 103) for discriminating either in favor of or against prior art references on the basis of nationality. *In re Moreton,* 288 F.2d 708, 129 USPQ 227 (CCPA 1961).

2121.01 Use of Prior Art in Rejections Where Operability Is in Question [R-3]

"In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention 'not novel' or 'anticipated' within section 102, the stated test is whether a reference contains an 'enabling disclosure'... ." *In re Hoeksema,* 399 F.2d 269, 158 USPQ 596 (CCPA 1968). The disclosure in an assertedly anticipating reference must provide an enabling disclosure of the desired subject matter; mere naming or description of the subject matter is insufficient, if it cannot be produced without undue experimentation. *Elan Pharm., Inc. v. **>Mayo Found. For Med. Educ. & Research<*, 346 F.3d 1051, 1054, 68 USPQ2d 1373, 1376 (Fed. Cir. 2003) (At issue was whether a prior art reference enabled one of ordinary skill in the art to produce Elan's claimed transgenic mouse without undue experimentation. Without a disclosure enabling one skilled in the art to produce a transgenic mouse without undue experimentation, the reference would not be applicable as prior art.). A reference contains an "enabling disclosure" if the public was in possession of the claimed invention before the date of invention. "Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his [or her] own knowledge to make the claimed invention." *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985).

I. 35 U.S.C. 102 REJECTIONS AND ADDITION OF EVIDENCE SHOWING REFERENCE IS OPERABLE

It is possible to make a 35 U.S.C. 102 rejection even if the reference does not itself teach one of ordinary skill how to practice the invention, i.e., how to make or use the article disclosed. If the reference teaches every claimed element of the article, secondary evidence, such as other patents or publications, can be cited to show public possession of the method of making and/or using. *In re Donohue,* 766 F.2d at 533, 226 USPQ at 621. See MPEP § 2131.01 for more information on 35 U.S.C. 102 rejections using secondary references to show that the primary reference contains an "enabling disclosure."

II. 35 U.S.C. 103 REJECTIONS AND USE OF INOPERATIVE PRIOR ART

"Even if a reference discloses an inoperative device, it is prior art for all that it teaches." *Beckman Instruments v. LKB Produkter AB*, 892 F.2d 1547, 1551, 13 USPQ2d 1301, 1304 (Fed. Cir. 1989). Therefore, "a non-enabling reference may qualify as prior art for the purpose of determining obviousness under 35 U.S.C. 103." *Symbol Techs. Inc. v. Opticon Inc.*, 935 F.2d 1569, 1578, 19 USPQ2d 1241, 1247 (Fed. Cir. 1991).

2121.02 Compounds and Compositions — What Constitutes Enabling Prior Art [R-3]

>

I. < ONE OF ORDINARY SKILL IN THE ART MUST BE ABLE TO MAKE OR SYNTHESIZE

Where a process for making the compound is not developed until after the date of invention, the mere naming of a compound in a reference, without more, cannot constitute a description of the compound. *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968). Note, however, that a reference is presumed operable until applicant provides facts rebutting the presumption of *>operability<. *In re Sasse*, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Therefore, applicant must provide evidence showing that a process for making was not known at the time of the invention. See the following paragraph for the evidentiary standard to be applied.

>

II. < A REFERENCE DOES NOT CONTAIN AN "ENABLING DISCLOSURE" IF ATTEMPTS AT MAKING THE COMPOUND OR COMPOSITION WERE UNSUCCESSFUL BEFORE THE DATE OF INVENTION

When a prior art reference merely discloses the structure of the claimed compound, evidence showing that attempts to prepare that compound were unsuccessful before the date of invention will be adequate to show inoperability. *In re Wiggins,* 488 F.2d 538, 179 USPQ 421 (CCPA 1971). However, the fact that an author of a publication did not attempt to make the compound disclosed, without more, will not overcome a rejection based on that publication. *In re Donohue,* 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985) (In this case, the examiner had made a rejection under 35 U.S.C. 102(b) over a publication, which disclosed the claimed compound, in combination with two patents teaching a general process of making the particular class of compounds. The applicant submitted an affidavit stating that the authors of the publication had not actually synthesized the compound. The court held that the fact that the publication's author did not synthesize the disclosed compound was immaterial to the question of reference operability. The patents were evidence that synthesis methods were well known. The court distinguished *Wiggins*, in which a very similar rejection was reversed. In *Wiggins*, attempts to make the compounds using the prior art methods were all unsuccessful.). Compare *In re Hoeksema*, 399 F.2d 269, 158 USPQ 596 (CCPA 1968) (A claim to a compound was rejected over a patent to *De Boer* which disclosed compounds similar in structure to those claimed (obvious homologs) and a process of making these compounds. Applicant responded with an affidavit by an expert named Wiley which stated that there was no indication in the *De Boer* patent that the process disclosed in *De Boer* could be used to produce the claimed compound and that he did not believe that the process disclosed in *De Boer* could be adapted to the production of the claimed compound. The court held that the facts stated in this affidavit were legally sufficient to over-

circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

2163.07(b) Incorporation by Reference [R-3]

Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter. See >37 CFR 1.57 and< MPEP § 608.01(p) for Office policy regarding incorporation by reference. See MPEP § 2181 for the impact of incorporation by reference on the determination of whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph when 35 U.S.C. 112, sixth paragraph is invoked.

2164 The Enablement Requirement [R-2]

The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent.

The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. >However, to comply with 35 U.S.C. 112, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (an invention directed to a general system to improve the cleaning process for semiconductor wafers was enabled by a disclosure showing improvements in the overall system).< Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. A patent claim is invalid if it is not supported by an enabling disclosure.

The enablement requirement of 35 U.S.C. 112, first paragraph, is separate and distinct from the description requirement. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991) ("the purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'"). See also MPEP § 2161. Therefore, the fact that an additional limitation to a claim may lack descriptive support in the disclosure as originally filed does not necessarily mean that the limitation is also not enabled. In other words, the statement of a new limitation in and of itself may enable one skilled in the art to make and use the claim containing that limitation even though that limitation may not be described in the original disclosure. Consequently, such limitations must be analyzed for both enablement and description using their separate and distinct criteria.

Furthermore, when the subject matter is not in the specification portion of the application as filed but is in the claims, the limitation in and of itself may enable one skilled in the art to make and use the claim containing the limitation. When claimed subject matter is only presented in the claims and not in the specification portion of the application, the specification should be objected to for lacking the requisite support for the claimed subject matter using Form Paragraph 7.44. See MPEP § 2163.06. This is an objection to the specification only and enablement issues should be treated separately.

2164.01 Test of Enablement [R-5]

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the

circumstances is not sufficient.'" *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted).

2163.07(b) Incorporation by Reference [R-3]

Instead of repeating some information contained in another document, an application may attempt to incorporate the content of another document or part thereof by reference to the document in the text of the specification. The information incorporated is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. Replacing the identified material incorporated by reference with the actual text is not new matter. See >37 CFR 1.57 and< MPEP § 608.01(p) for Office policy regarding incorporation by reference. See MPEP § 2181 for the impact of incorporation by reference on the determination of whether applicant has complied with the requirements of 35 U.S.C. 112, second paragraph when 35 U.S.C. 112, sixth paragraph is invoked.

2164 The Enablement Requirement [R-2]

The enablement requirement refers to the requirement of 35 U.S.C. 112, first paragraph that the specification describe how to make and how to use the invention. The invention that one skilled in the art must be enabled to make and use is that defined by the claim(s) of the particular application or patent.

The purpose of the requirement that the specification describe the invention in such terms that one skilled in the art can make and use the claimed invention is to ensure that the invention is communicated to the interested public in a meaningful way. The information contained in the disclosure of an application must be sufficient to inform those skilled in the relevant art how to both make and use the claimed invention. >However, to comply with 35 U.S.C. 112, first paragraph, it is not necessary to "enable one of ordinary skill in the art to make and use a perfected, commercially viable embodiment absent a claim limitation to that effect." *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1338, 68 USPQ2d 1940, 1944 (Fed. Cir. 2003) (an invention directed to a general system to improve the cleaning process for semiconductor wafers was enabled by a disclosure showing improvements in the overall system).< Detailed procedures for making and using the invention may not be necessary if the description of the invention itself is sufficient to permit those skilled in the art to make and use the invention. A patent claim is invalid if it is not supported by an enabling disclosure.

The enablement requirement of 35 U.S.C. 112, first paragraph, is separate and distinct from the description requirement. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563, 19 USPQ2d 1111, 1116-17 (Fed. Cir. 1991) ("the purpose of the 'written description' requirement is broader than to merely explain how to 'make and use'"). See also MPEP § 2161. Therefore, the fact that an additional limitation to a claim may lack descriptive support in the disclosure as originally filed does not necessarily mean that the limitation is also not enabled. In other words, the statement of a new limitation in and of itself may enable one skilled in the art to make and use the claim containing that limitation even though that limitation may not be described in the original disclosure. Consequently, such limitations must be analyzed for both enablement and description using their separate and distinct criteria.

Furthermore, when the subject matter is not in the specification portion of the application as filed but is in the claims, the limitation in and of itself may enable one skilled in the art to make and use the claim containing the limitation. When claimed subject matter is only presented in the claims and not in the specification portion of the application, the specification should be objected to for lacking the requisite support for the claimed subject matter using Form Paragraph 7.44. See MPEP § 2163.06. This is an objection to the specification only and enablement issues should be treated separately.

2164.01 Test of Enablement [R-5]

Any analysis of whether a particular claim is supported by the disclosure in an application requires a determination of whether that disclosure, when filed, contained sufficient information regarding the subject matter of the claims as to enable one skilled in the pertinent art to make and use the claimed invention. The standard for determining whether the

specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde,* 242 U.S. 261, 270 (1916) which postured the question: is the experimentation needed to practice the invention undue or unreasonable? That standard is still the one to be applied. *In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). Accordingly, even though the statute does not use the term "undue experimentation," it has been interpreted to require that the claimed invention be enabled so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). See also *United States v. Telectronics, Inc.*, 857 F.2d 778, 785, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988) ("The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation."). A patent need not teach, and preferably omits, what is well known in the art. *In re Buchner*, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); and *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed. Cir. 1984). >Any part of the specification can support an enabling disclosure, even a background section that discusses, or even disparages, the subject matter disclosed therein. *Callicrate v. Wadsworth Mfg., Inc.*, 427 F.3d 1361, 77 USPQ2d 1041 (Fed. Cir. 2005)(discussion of problems with a prior art feature does not mean that one of ordinary skill in the art would not know how to make and use this feature).< Determining enablement is a question of law based on underlying factual findings. *In re Vaeck*, 947 F.2d 488, 495, 20 USPQ2d 1438, 1444 (Fed. Cir. 1991); *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed. Cir. 1984).

UNDUE EXPERIMENTATION

The fact that experimentation may be complex does not necessarily make it undue, if the art typically engages in such experimentation. *In re Certain Limited-Charge Cell Culture Microcarriers*, 221 USPQ 1165, 1174 (Int'l Trade Comm'n 1983), *aff'd. sub nom., Massachusetts Institute of Technology v. A.B. Fortia*, 774 F.2d 1104, 227 USPQ 428 (Fed. Cir. 1985). See also *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404. The test of enablement is not whether any experimentation is necessary, but whether, if experimentation is necessary, it is undue. *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976).

2164.01(a) Undue Experimentation Factors

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue." These factors include, but are not limited to:

(A) The breadth of the claims;

(B) The nature of the invention;

(C) The state of the prior art;

(D) The level of one of ordinary skill;

(E) The level of predictability in the art;

(F) The amount of direction provided by the inventor;

(G) The existence of working examples; and

(H) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (reversing the PTO's determination that claims directed to methods for detection of hepatitis B surface antigens did not satisfy the enablement requirement). In *Wands*, the court noted that there was no disagreement as to the facts, but merely a disagreement as to the interpretation of the data and the conclusion to be made from the facts. *In re Wands,* 858 F.2d at 736-40, 8 USPQ2d at 1403-07. The Court held that the specification was enabling with respect to the claims at issue and found that "there was considerable direction and guidance" in the specification; there was "a high level of skill in the art at the time the application was filed;" and "all of the methods needed to practice the invention were well known." 858 F.2d at 740, 8 USPQ2d at 1406. After considering all the factors related to the enablement issue, the court concluded that "it would not require undue experimentation to obtain antibodies needed to practice the claimed invention." *Id.*, 8 USPQ2d at 1407.

158 USPQ 596
In re HOEKSEMA
U.S. Court of Customs and Patent Appeals

No. 7778

Decided August 8, 1968

399 F2d 269

Headnotes

PATENTS

[1] Rehearing and reopening—In general (▶ 57.1)

Court of Customs and Patent Appeals grants rehearing because of continuing importance of questions involved and strong suggestion of error in its earlier opinion.—In re Hoeksema (CCPA) 158 USPQ 596.

[2] Patentability—Composition of matter (▶ 51.30)

Process obviousness is relevant in deciding compound obviousness.—In re Hoeksema (CCPA) 158 USPQ 596.

[3] Patentability—Invention—In general (▶ 51.501)

In context of 35 U.S.C. 103, court is not permitted to fragment a claimed invention in applying that section; invention must be considered as a whole.—In re Hoeksema (CCPA) 158 USPQ 596.

[4] Patentability — Composition of matter (▶ 51.30)

Claimed compound is the invention as a whole (35 U.S.C. 103), but, so considered, unless there is some known or obvious way to make compound, invention is nothing more than a mental concept expressed in chemical terms and formulae on a paper; invention as a whole is claimed compound and a way to produce it; since there is no showing that claimed compound can exist because there is no showing of a known or obvious way to manufacture it, the invention as a whole is not obvious under section 103.—In re Hoeksema (CCPA) 158 USPQ 596.

[5] Patentability — Anticipation — In general (▶ 51.201)

Patentability — Invention—In general (▶ 51.501)

Conditions for patentability, novelty and loss of right to patent, stated in 35 U.S.C. 102, may have relevance as to disclosure which must be found in prior art to find obviousness of invention under section 103; in determining that quantum of prior art disclosure which is necessary to declare applicant's invention "not novel" or "anticipated" within section 102, test is whether reference contains an enabling disclosure; this test applies to issues under section 103.—In re Hoeksema (CCPA) 158 USPQ 596.

[6] Patentability—Composition of matter (▶ 51.30)

If prior art fails to disclose or render obvious a method for making claimed compound, at time invention was made, it may not be legally concluded that compound itself is in possession of public; absence of known or obvious process for making claimed compounds overcomes presumption that compounds are obvious, based on close relationships between their structures and those of prior art compounds.—In re Hoeksema (CCPA) 158 USPQ 596.

[7] Pleading and practice in Patent Office—Rejections (▶ 54.7)

Patent Office having cited reference which rendered claimed compounds prima facie obvious, applicant sustained burden of going forward with contrary evidence by filing affidavit pointing out that reference does not disclose process for producing claimed compounds, thus overcoming Office's position as to reference's legal effect under 35 U.S.C. 103; thereupon, burden of going forward with proofs to support its position as to obviousness shifted to Office; Office's failure to produce such evidence requires that rejection be *reversed.*—In re Hoeksema (CCPA) 158 USPQ 596.

Particular Patents

Particular patents —9-D-Psicofuranosylpurine

Hoeksema, 9-D-Psicofuranosylpurine and 6-Substituted Derivatives, claim 1 of application allowed.—In re Hoeksema (CCPA) 158 USPQ 596.

Case History and Disposition

Page 597

Appeal from Board of Appeals of the Patent Office.

Application for patent of Herman Hoeksema, Serial No. 30,770, filed May 23, 1960; Patent Office Group 120. From decision rejecting claim 1, applicant appeals. Affirmed at 154 USPQ 169 . On petition for rehearing. Reversed; Kirkpatrick, Judge, dissenting with opinion.

Attorneys

EARL C. SPAETH (EUGENE O. RETTER and GEORGE T. JOHANNESEN of counsel) all of Kalamazoo, Mich., for appellant.

JOSEPH SCHIMMEL (JACK E. ARMORE of counsel) for Commissioner of Patents.

Judge

Before WORLEY, Chief Judge, RICH, SMITH, and ALMOND, Associate Judges, and KIRKPATRICK, Judge. *

* Senior District Judge, Eastern District of Pennsylvania, sitting by designation.

Opinion Text

Opinion By:

SMITH, Judge.

[1] In our prior consideration of this appeal, we *affirmed* the decision of the Patent Office Board of Appeals, which had *affirmed* the examiner's rejection of the sole remaining claim of appellant's application, [1] In re Hoeksema, 54 CCPA 1618, 379 F.2d 1007, 154 USPQ 169 (1967). Because of the continuing importance of the questions involved, and the strong suggestion of error in our earlier opinion, we granted appellant's petition for a rehearing under the provisions of Rule 7 of this court, 55 CCPA—, (October 5, 1967).

[1] Claim 1 in Serial No. 30,770, filed May 23, 1960, for "9-D-Psicofuranosylpurine and 6-Substituted Derivatives." Claims 2 and 11-25 stand allowed.

The parties filed new briefs, and the case was re*argued* on January 3, 1968. Upo*n reconsideration* of our previous decision, we have concluded that our previous decision was erroneous and that a proper resolution of the issues requires that we *reverse* the decision of the board.

The facts are set forth in our original opinion. We shall assume familiarity with that statement of facts

and shall here redevelop only those which we now believe were previously misapprehended or misapplied and require the present decision.

The sole claim on appeal is directed to a chemical compound and reads as follows:

1. An N-psicofuranoside having the formula:

Page 598

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA at 1-800-372-1033.

wherein A is selected from the class consisting of hydrogen, the group -XR wherein R is selected from the class consisting of hydrogen, lower-alkyl, and lower-aralkyl, and X is selected from the class consisting of oxygen and sulfur, and the group

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA at 1-800-372-1033.

wherein R_2 is selected from the class consisting of hydrogen, lower-alkyl, lower-aralkyl, and lower-aryl, and R_3 is selected from the class consisting of lower-alkyl, lower-aralkyl, and lower-aryl, and R¢is selected from the class consisting of hydrogen, a hydrocarbon carboxylic acid acyl radical containing from two to twelve carbon atoms, inclusive, and a halo-, hydroxy-, lower-alkoxy-, amino-, cyano-, thiocyano-, and nitro-substituted hydrocarbon carboxylic acid acyl radical containing from two to twelve carbon atoms, inclusive.

That claim stands rejected under 35 U.S.C. 103 as unpatentable over prior art, on this record limited solely to the De Boer et al. patent [2] (De Boer) which discloses a compound with the structural formula:

[2] Patent No. 3,094,460, issued June 18, 1963 on an application filed January 20, 1959.

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA at 1-800-372-1033.

As we noted in our original opinion, the controversy here is limited to the substituent A at the 6-position of the purine ring system. Although a compound having De Boer's structure is not included in the appealed claim since A in the claim cannot be an unsubstituted or primary amino,

Graphic material consisting of a chemical formula or diagram set at this point is not available. See text in hard copy or call BNA at 1-800-372-1033.

, the basic structure of the De Boer compound is similar to the structure of appellant's alkylamino and dialkylamino compounds. [3]

[3] Appellant, in effect, admits that there is such a "structural similarity" between his claimed compounds and the prior art compounds as to raise an "inference of fact" that they are not patentable within the meaning of 35 U.S.C. 103. See In re Papesch, 50 CCPA 1084, 315 F.2d 381, 137 USPQ 43 (1963); In re Victor Mills, 47 CCPA 1185, 281 F.2d 218, 126 USPQ 513 (1960).

Despite this close structural similarity between the De Boer amino compound and the alkylamino and dialkylamino compounds included in the appealed claim, appellant chose not to submit a showing of unexpected properties in his claimed compounds. [4] Appellant asserted that his compounds were unobvious and patentable without such a showing. He urged that De Boer does not teach one of ordinary skill in the art how to make appellant's claimed compounds, and the examiner did not cite any other reference telling how they might be made. Therefore, in appellant's view, his claimed compounds are not in possession of the public, In re Brown, 51 CCPA 1254, 329 F.2d 1066, 141 USPQ 245 (1964). [5]

[4] Such a showing often has been treated by this court as overcoming a case of "prima facie obviousness" or the "inference of fact" that the compounds are obvious. See, e.g., In re Papesch, supra note 3 and cases cited therein.

[5] For the applicability of In re Brown, supra, to other factual contexts, see In re Bird, 52 CCPA 1290, 1294, 344 F.2d 979, 982, 145 USPQ 418, 420 (1965); In re Sheppard, 52 CCPA 859, 864,

339 F.2d 238, 242, 144 USPQ 42, 45 (1964); Dix-Seal Corp. v. New Haven Trap Rock Co., 236 F.Supp. 914, 921, 144 USPQ 57, 64 (D.C. Conn. 1964).

In support of his position, appellant submitted an affidavit by Dr. Paul F. Wiley relating to the unavailability to the public of processes for preparing appellant's alkylamino and dialkylamino compounds. [6] Dr. Wiley's qualifications

Page 599

and competence as an expert to state facts and opinion in this area of chemistry were not challenged.

[6] After setting forth his qualifications and stating that he had read and understood both appellant's application and the prior art patent, Dr. Wiley stated:

> THAT, 6-amino-9-D-psicofuranosylpurine is a systematic name for "psicofuranine" which is disclosed in column 6, lines 46-62 of the aforesaid patent;
>
> THAT, according to the aforesaid patent, 6-amino-9-D-psicofuranosylpurine is produced by a fermentation process involving the action of a specific micro-organism, S, hygroscopicus var. decoyinine, in certain aqueous nutrient media;
>
> THAT, *there is no indication in the aforesaid patent* [De Boer] *that the aforesaid fermentation process could be used to produce 6-lower-alkylamino-9-D-psicofuranosylpurines, 6-di-lower-alkylamino-9-D-psicofuranosylpurines, or other 6-substituted-amino-9-D-piscofuranosylpurines;*
>
> THAT, he does not believe the aforesaid fermentation process could be adapted to the production of the aforesaid 6-lower-alkylamino-9-D-psicofuranosylpurines, 6-di-lower-alkyamino-9-D - psicofuranosylpurines, or other 6-substituted-amino-9-D-psicofuranosylpurines;
>
> THAT, *the aforesaid 6-amino-9-psicofuranosylpurine could not be transformed by direct chemical substitution of the 6-amino group to a 6-lower-alkylamino-9-D-psicofuranosylpurine,* a 6-di-lower alkylamino-9-D-psicofuranosylpurine, or other 6-substituted-amino-9-D-psicofuranosylpurines, *and that such transformations could be carried out only by a complex multi-step procedure such as that described in the aforesaid patent application Serial No. 30,770.* [Emphasis added.]

Regarding the Wiley affidavit, the examiner stated, in his Answer:

> The affidavit * * * does not appear to be pertinent to the claim now on appeal because it is directed to the processes by which the De Boer et al. and appellant's compounds are prepared, and shows nothing unobvious for the instantly claimed compound.

Concerning the Wiley affidavit, the board cited a statement of this court in In re Riden, 50 CCPA 1411, 318 F.2d 761, 138 USPQ 112 (1963), to the effect that "the method of making the compounds is a relevant fact to be considered in the question of obviousness of the compounds," 50 CCPA at 1415, 318 F.2d at 764, 138 USPQ at 114-115. But the board continued:

> * * * This may be so but it is only one factor and, in our opinion, should never be the overriding one which appellant is here, in effect, urging.

Appellant states the first of two central questions to be decided in this rehearing as follows:

> 1) Appellant will admit his compounds are obvious and unpatentable *if* an obvious process is available to make them. Does it follow then that appellant's compounds are unobvious and patentable if an obvious process is *not* available to make them?

[2] Within this context, appellant simplifies that question to: Is process obviousness relevant in deciding compound obviousness? [7]

[7] To this extent, appellant has misstated his argument. That process obviousness is relevant in this context is clear from In re Riden, supra. See also In re Chapman, 53 CCPA 978, 357 F.2d 418, 148 USPQ 711 (1966); In re Burt, 53 CCPA 929, 356 F.2d 115, 148 USPQ 548 (1966); In re

> Schechter, 40 CCPA 1009, 205 F.2d 185, 98 USPQ 144 (1963).
>
> We think appellant really means to say that the question is whether a claimed compound may be said to be legally obvious when no process for making that compound is shown in the prior art relied upon to establish legal obviousness under section 103.

The solicitor responds to the latter characterization of the question in the affirmative, pointing out that the first question bears on the principle implicit in In re Brown, supra, that claimed compounds not distinguished in their properties over closely related prior art compounds are unpatentable thereover where the claimed compounds would be "in possession of the public" in that a process for preparing them would be obvious to those of ordinary skill in the art.

In addition, the solicitor now refers to our prior opinion in which we noted that the facts in this case are closely analogous to those of In re Riden, supra, where we stated that the fact that the method of making the claimed compound is relevant, 54 CCPA at—, 379 F.2d at 1010, 154 USPQ at 172.

A recurring problem of analysis which confronted us as we prepared our previous opinion, and which still confronts us after the rehearing, has its genesis in a proper understanding of the issue as framed by appellant. In effect, appellant agrees that since the claimed product is a homolog of a known compound, it would be prima facie "obvious" under 35 U.S.C. 103. But this agreement is conditioned on the proviso that there is in the prior art an "obvious" process by which to make that compound.

[3] In the context of section 103, we are not permitted to fragment a claimed invention in applying that section. The clear mandate of the statute which governs our analysis requires that

Page 600

we consider the *invention as a whole* in making the determination.

[4] Thus, as we apply the statute to the present invention, we must ask first, what is the invention as a whole? Necessarily, by elementary patent law principles, it is the claimed compound, but, so considered, unless there is some known or obvious way to make the compound, the invention is nothing more than a mental concept expressed in chemical terms and formulae on a paper.

We are certain, however, that the invention as a whole is the claimed compound *and* a way to produce it, wherefore appellant's argument has substance. There has been no showing by the Patent Office in this record that the claimed compound can exist because there is no showing of a known or obvious way to manufacture it; hence, it seems to us that the "invention as a whole," which section 103 demands that we consider, is not obvious from the prior art of record.

While there are valid reasons based in public policy as to why this defect in the prior art precludes a finding of obviousness under section 103, In re Brown, supra, its immediate significance in the present inquiry is that it poses yet *another difference* between the claimed invention and the prior art which *must* be considered in the context of section 103. So considered, we think the differences between appellant's *invention as a whole* and the prior art are such that the claimed invention would not be obvious within the contemplation of 35 U.S.C. 103.

[5] While 35 U.S.C. 102 is not *directly* involved in the issue on review, the conditions for patentability, novelty and loss of right to patent, there stated, may have relevance as to the disclosure which must be found in the prior art to find obviousness of an invention under section 103. In determining that quantum of prior art disclosure which is necessary to declare an applicant's invention "not novel" or "anticipated" within section 102, the stated test is whether a reference contains an "enabling disclosure," in the present context, a process by which the claimed compound could be made. In In re LeGrice, 49 CCPA 1124, 301 F.2d 929, 133 USPQ 365 (1962), we observed that the resolution of this issue required us to determine whether, *as a matter of law,* a reference without such a disclosure constituted a statutory time bar to an applicant's right to a patent. There, the issue was founded on 35 U.S.C. 102(b), not 103, but our conclusions have a certain pertinence here. We concluded, id. at 1134, 301 F.2d at 936, 133 USPQ at 372:

> We think it is sound law, consistent with the public policy underlying our patent law, that before any publication can amount to a statutory bar to the grant of a patent, its disclosure must be such that a skilled artisan could take its teachings in *combination with his own knowledge of the particular art and be in possession of the invention.* * * *

In In re Brown, supra, this court discussed In re Von Bramer, 29 CCPA 1018, 127 F.2d 149, 53 USPQ 345 (1942), commenting that that opinion should not be construed to encompass what had come to be called the "Von Bramer doctrine." There we stated, 51 CCPA at 1257, 329 F.2d at 1009, 141 USPQ at 247:

> * * * This doctrine, which appears to have resulted from In re Von Bramer et al., supra, seems over a period of years to have been tailored in some quarters to a principle which defeats the novelty of a chemical compound on the basis of a mere printed conception or a mere printed contemplation of a chemical "compound" *irrespective of the fact* that so-called "compound" *described in the reference is not in existence or that there is no process shown in the reference for preparing the compound, or that there is no process known to a person having ordinary skill in the relevant art for preparing the compound.* In other words, a mere formula or a mere sequence of letters which constitute the designation of a "compound," is considered adequate to show that a compound in an application before the Patent Office, which compound is designated by the same formula or the same sequence of letters, is old. We do not think that the Von Bramer case should be so construed. [Emphasis added.]
>
> To the extent that anyone may draw an inference from the Von Bramer case that the *mere* printed conception or the *mere* printed contemplation which constitutes the designation of a "compound" is sufficient to show that such a compound is old, regardless of whether the compound is involved in a 35 U.S.C. 102 or 35 U.S.C. 103 rejection, we totally disagree. * * * [Footnotes omitted.]

We concluded, relying on In re Le Grice, supra, and E. I. du Pont de Nemours & Co. v. Ladd, 328 F.2d 547, 140 USPQ 297 (D.C. Cir. 1964), that the "true test of any prior art relied on to show or suggest that a chemical compound is old, is whether the prior

Page 601

art is such as to place the disclosed 'compound' in the *possession of the public.* " 51 CCPA at 1259, 329 F.2d at 1011, 141 USPQ at 249.

While In re Le Grice was bottomed on an issue arising under 35 U.S.C. 102 where the reference was a "printed publication," that test, in our view, is also properly applicable to issues arising under 35 U.S.C. 103. See In re Brown, supra (pertinent portion quoted above); Deutsche Gold-Und Silber-Scheideanstalt v. Commissioner, 251 F.Supp. 624, 629-630, 148 USPQ 412, 416 (D.D.C. 1966), *affirmed*, __F.2d__, 157 USPQ 549 (D.C. Cir. 1968).

[6] Thus, upon careful *reconsideration* it is our view that if the prior art of record fails to disclose or render obvious a method for making a claimed compound, at the time the invention was made, it may not be legally concluded that the compound itself is in the possession of the public. [8] In this context, we say that the absence of a known or obvious process for making the claimed compounds overcomes a presumption that the compounds are obvious, based on close relationships between their structures and those of prior art compounds.

---

[8] In Phillips Petroleum v. Ladd, 219 F.Supp. 366, 138 USPQ 421 (D.D.C. 1963), in considering a rejection arising under 35 U.S.C. 102, the District Court agreed with this court that the mere naked statement of the invention does not put anyone in possession of the invention. That court was careful to note that no process had been shown in the reference for preparing the compound and that no process was known to one of ordinary skill in the art for preparing the compound.

In Ex parte Wall, 156 USPQ 95 (P.O. Bd. App. 1964), the board considered a rejection under 35 U.S.C. 102 of a claim reading "Perfluorostyrene." In reversing the examiner, the board commented that the examiner did not contend that the reference disclosed how perfluorostyrene is made, nor did he point to any extraneous evidence which would indicate that those skilled in the art knew how to make that compound.

The second aspect of the questions presented by this rehearing involves the issue of whether the burden is on the Patent Office to provide the evidence on which to predicate process obviousness.

35 U.S.C. 101 states, in its preamble, that an applicant is *entitled* to a patent *unless* certain patent-defeating provisions are met. The substantive patent-defeating provisions are encompassed in 35 U.S.C. 100-103.

[7] As we have stated, the Patent Office search resulted in citation of the De Boer reference which, under the prevailing law, rendered appellant's claimed compounds prima facie obvious. In other words, its citation shifted to appellant the burden of going forward with contrary evidence. Appellant filed the affidavit of Dr. Wiley which points out as a fact that De Boer—the only reference being relied on—does not disclose a process for producing the different compounds here claimed.

We think that portion of the Wiley affidavit set forth, supra note 6, states facts which were legally sufficient to overcome the position of the Patent Office as to the legal effect under section 103 of the De Boer reference. [9] Appellant's responsibility to overcome this reference as a "patent-defeating" reference under section 103 at that point in the prosecution was only to overcome De Boer as a reference pertinent to the issue of obviousness under section 103.

---

[9] We think this approach to be eminently fair to all parties and in accord with the opinion of the Supreme Court in Graham, in its requiring that all of the pertinent evidence be considered while yet leaving the primary responsibility for sifting out unpatentable material with the Patent Office, Graham v. John Deere Co., 383 U.S. 1 at 18, 148 USPQ at 467.

It would be practically impossible for an applicant to show that all known processes are incapable of producing the claimed compound.

We think the Wiley affidavit is clearly sufficient for this purpose. The affidavit points out that there is no indication in the De Boer patent that the fermentation process used to produce De Boer's compounds could be used to produce appellant's compounds. Since we are of the view that the method for making the compounds is an integral part of the "invention as a whole" which we must consider under section 103, we conclude that the burden of going forward with proofs to support its position as to obviousness of the claimed invention shifted to the Patent Office upon appellant's filing of the Wiley affidavit.

The failure of the Patent Office to produce such evidence requires that the decision of the board be reversed.

WORLEY, Chief Judge, did not participate.

Dissenting Opinion Text

Dissent By:

KIRKPATRICK, Judge, dissenting.

I am unable to agree with the result reached by the majority. The reasons for my dissent appear in the *overruled* opinion In re Hoeksema, 54 CCPA 1618, 379 F.2d 1007, 154 USPQ 169 (1967).

- End of Case -

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > Elan Pharmaceuticals Inc Foundation for Medical Education and Research, 68 USPQ2d 1373 (Fed. Cir. 2003)

68 USPQ2d 1373

Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research

U.S. Court of Appeals Federal Circuit

No. 00-1467

Decided October 2, 2003

346 F3d 1051

Headnotes

PATENTS

[1] Patentability/Validity — Anticipation — Prior art (▶115.0703)

Patentability/Validity — Specification — Enablement (▶115.1105)

Disclosure of assertedly anticipating prior art reference must be adequate to enable possession of desired subject matter, and reference that names or describes desired subject matter thus does not anticipate if subject matter cannot be produced without undue experimentation; in present case, summary judgment

Page 1374

that patents for transgenic animals harboring amyloid precursor protein allele having "Swedish mutation" are anticipated by prior art reference must be vacated and remanded for determination of whether reference enabled persons of ordinary skill in field of invention to make desired transgenic mouse without undue experimentation, since federal district court did not directly address question of enablement, which was not subject of summary judgment motion.

Particular Patents

Particular patents — Chemical — Transgenic animals

5,612,486, McConlogue and Zhao, transgenic animals harboring APP allele having Swedish mutation, summary judgment of invalidity reversed.

5,850,003, McConlogue and Zhao, transgenic rodents harboring APP allele having Swedish mutation, summary judgment of invalidity reversed.

Case History and Disposition

Appeal from the U.S. District Court for the Northern District of California, Alsup, J.

Action by Elan Pharmaceuticals Inc. and Athena Neurosciences Inc. against Mayo Foundation for Medical Education and Research for patent infringement. Plaintiffs appealed from summary judgment holding patents in suit invalid for anticipation. Initial opinion on appeal (64 USPQ2d 1292) was vacated, and is replaced with present opinion. Summary judgment of invalidity reversed and remanded.

Attorneys

Lynn H. Pasahow and Charlene M. Morrow, of Fenwick & West, Mountain View, Calif.; Beth H. Parker, Mary T. Huser, and S. Christian Platt, of Bingham McCutchen, Palo Alto, Calif.; Thomas S. Hixson, of

Bingham McCutchen, San Francisco, Calif., for plaintiffs-appellants.

Robert E. Hillman, of Fish & Richardson, Boston, Mass.; Shelley K. Wessels, Karen I. Boyd, and Kurtis D. MacFerrin, of Fish & Richardson, Menlo Park, Calif.; Chad A. Hanson, of Fish & Richardson, Minneapolis, Minn., for defendant-appellee.

Judge

Before Newman, Gajarsa, and Dyk, circuit judges.

Opinion Text

Opinion By:

Newman, J.

The initial opinion in this appeal, reported at *Elan Pharmaceuticals, Inc. v. Mayo Foundation*, 304 F.3d 1221, 64 USPQ2d 1292 (Fed. Cir. 2002), has been vacated, 314 F.3d 1299 (Fed. Cir. 2002) (*en banc*) and is replaced with this opinion and decision.

The United States District Court for the Northern District of California, granting the Mayo Foundation's motion for summary judgment of patent invalidity, held that Elan's two patents in suit, United States Patent No. 5,612,486 (the '486 patent) for "Transgenic Animals Harboring APP Allele Having Swedish Mutation," and Patent No. 5,850,003 (the '003 patent) for "Transgenic Rodents Harboring APP Allele Having Swedish Mutation," are invalid on the ground of anticipation by United States Patent No. 5,455,169 entitled "Nucleic Acids for Diagnosing and Modeling Alzheimer's Disease" (the Mullan reference). [1]

[1] *Elan Pharmaceuticals, Inc. v. Mayo Foundation for Medical Education & Research*, 175 F.Supp.2d 1209 (N.D. Cal. 2000).

In response to the questions raised in the petitions for reconsideration, we clarify that invalidity based on anticipation requires that the assertedly anticipating disclosure enabled the subject matter of the reference and thus of the patented invention without undue experimentation. Applying this rule, we remand for determination of whether the Mullan reference was an enabling disclosure. The summary judgment is reversed, and the case is remanded for further proceedings.

BACKGROUND

At the time of the Elan invention it was known that the brains of people with Alzheimer's disease contain abnormal tangles and deposits of plaques, and that a principal component of the plaques is a protein fragment called beta-amyloid peptide or betaAP (also designated βAP and Aβ). The formation of betaAP in brain tissue is believed to induce or foster formation of Alzheimer's disease plaques.

It is believed that a mechanism by which betaAP is formed is the abnormal cleavage of a protein produced in brain cells, called the amyloid precursor protein (APP); and that this abnormal cleavage occurs when an enzyme produced in the brain, called beta-secretase, cleaves the APP molecule between amino acids 596 and 597; and a second enzyme produced

Page 1375

in the brain, called gamma-secretase, releases the betaAP fragment from a portion of the cleaved APP. The mechanism is illustrated in the Elan brief as follows:

Fig.1 - Processi

Humans who do not develop Alzheimer's disease are believed to break down the APP in a manner that does not form significant amounts of betaAP in the brain.

The Swedish mutation is an abnormal gene [2] that was discovered on chromosome 21 in a Swedish family that has an unusually high incidence of early-onset Alzheimer's disease. This mutation is described in the Mullan patent as a variation in the DNA nucleotides that encode codons 670 and 671, [3] wherein lysine and methionine, the amino acids normally encoded at these positions, are replaced with asparagine and leucine.

---

[2] A gene is a segment of DNA that encodes for and leads to the production, through several complex steps, of the sequence of amino acids that constitutes a protein. A mutation is a change in the gene DNA and the changes in the ensuing products. *See* Bruce Alberts et al., *Essential Cell Biology* (1998), Ch.6 "DNA," Ch.7 "From DNA to Protein."

[3] The positions at codons 670/671 (Mullan) and codons 596/597 (Elan) are the same, due to differing starting points in the APP chain. *See* '486 patent, col. 11, lines 29-34.

The Elan patents are directed to transgenic rodents whose genetic makeup has been modified to include the Swedish mutation. Claim 1 of the '486 patent is representative:

> 1. A transgenic rodent comprising
>
> a diploid genome comprising a transgene encoding a heterologous APP polypeptide having the Swedish mutation wherein the amino acid residues at positions corresponding to positions 595 and 596 in human APP695 are asparagine and leucine, respectively,
>
> wherein the transgene is expressed to produce a human APP polypeptide having the Swedish mutation,
>
> and wherein said polypeptide is processed to ATF-betaAPP in a sufficient amount to be detectable in a brain homogenate of said transgenic rodent.

Dependent claims add the limitations that the rodent is murine (mouse) and that the transgene is nonhomologously integrated.

The claims of the '003 patent differ only in that they include a promoter and a polyadenylation site. Claim 1 is representative:

> 1. A transgenic rodent comprising
>
> a diploid genome comprising a transgene comprising in operable linkage a promoter, a DNA segment encoding a heterologous APP polypeptide and a polyadenlyation site,
>
> wherein the APP polypeptide has the Swedish mutation whereby the amino acid residues at positions corresponding to positions 595 and 596 in human APP695 are asparagine and leucine, respectively,
>
> wherein the transgene is expressed to produce a human APP polypeptide having the Swedish mutation,
>
> and wherein said polypeptide is processed to ATF-betaAPP in a sufficient amount to be detectable in a brain homogenate of said transgenic rodent.

The Mullan reference was cited as prior art in prosecution of the Elan patents, and was distinguished upon amendment of the Elan claims to include the claim clause that refers to production of ATF-betaAPP in detectable amounts in the rodent brain.

I

The district court, granting Mayo's motion for summary judgment, held that the Mullan reference anticipates the Elan invention. Whether an invention is anticipated is a question of fact. *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302, 36 USPQ2d 1101, 1103 (Fed. Cir. 1995). On appeal, Elan requests review of the district court's determination that the Mullan reference anticipates the claims of the Elan patent because the Elan mouse is inherent in Mullan. We conclude that Elan's arguments are more properly characterized as enablement arguments rather than inherency arguments.

To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art

Page 1376

are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). *See Bristol-Myers Squibb v. Ben Venue Laboratories, Inc.*, 246 F.3d 1368, 1374, 58 USPQ2d 1508, 1512 (Fed. Cir. 2001) ("To anticipate the reference must also enable one of skill in the art to make and use the claimed invention."); *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558, 1566, 37 USPQ2d 1618, 1624 (Fed. Cir. 1996) ("To anticipate a claim, a reference must disclose every element of the challenged claim and enable one skilled in the art to make the anticipating subject matter."). Review of Elan's opposition to Mayo's motion for summary judgment shows that, while Elan purports to contest Mayo's motion on the grounds that the Mullan patent does not inherently anticipate the Elan claimed mouse, the language and factual basis of this argument encompass enablement.

Enablement requires that "the prior art reference must teach one of ordinary skill in the art to make or carry out the claimed invention without undue experimentation." *Minnesota Mining and Manufacturing Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301, 64 USPQ2d 1270, 1278 (Fed. Cir. 2002); *Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1369, 52 USPQ2d 1129, 1134 (Fed. Cir. 1999) ("Whether undue experimentation would have been required to make and use an invention, and thus whether a disclosure is enabling under 35 U.S.C. §112, ¶ 1, is a question of law that we review de novo, based on underlying factual inquiries that we review for clear error.").

The factual premises of the enablement analysis for biological processes were addressed in *In re Wands*, 858 F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988), the court explaining that determination of whether the requisite amount of experimentation is undue may include consideration of:

> (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. at 737; 8 USPQ2d at 1404. *See Amgen, Inc. v. Chugai Pharm. Co.*, 727 F.2d 1200, 1213, 18 USPQ2d 1016, 1027 (Fed. Cir. 1991) (discussing application of the *Wands* factors). In *In re Goodman*, 11 F.3d 1046, 1052, 29 USPQ2d 2010, 2015 (Fed. Cir. 1993) the *Wands* factors were applied to a gene transformation method, the court finding that the method "would have required extensive experimentation that would preclude patentability."

[1] The disclosure in an assertedly anticipating reference must be adequate to enable possession of the desired subject matter. It is insufficient to name or describe the desired subject matter, if it cannot be produced without undue experimentation. The principles underlying application of the criteria of enablement to the content of the prior art were discussed in *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985):

> It is well settled that prior art under 35 U.S.C. §102(b) must sufficiently describe the claimed invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling. It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.

Id. at 533, 226 USPQ at 621. *See also In re Borst*, 345 F.2d 851, 855, 145 USPQ 554, 557 (CCPA 1962) ("the disclosure must be such as will give possession of the invention to the person of ordinary skill. Even the act of publication or the fiction of constructive reduction to practice will not suffice if the disclosure does not meet this standard.").

The determination of what level of experimentation is "undue," so as to render a disclosure non-enabling, is made from the viewpoint of persons experienced in the field of the invention. *See Enzo Biochem*, 188 F.3d at 1373-74 (discussing evidence of enablement and nonenablement in an unpredictable field of biotechnology). "The determination of what constitutes undue experimentation

in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art." *In re Wands*, 858 F.2d 731, 737 [8

Page 1377

USPQ2d 1400] (Fed. Cir. 1988). In *Wands* the court observed that "[t]he test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed ...." *Id.*, *quoting In re Jackson*, 217 USPQ 804, 817 (Bd. App. 1982).

The Mullan reference contains an extensive description of the Swedish mutated gene, its source, the nature of the mutation, and its role in Alzheimer's disease. The reference also states that the invention provides a transgenic animal whose cells contain the mutated gene and express the Swedish mutated protein:

> The invention also provides a transgenic non-human animal containing, in a germ or somatic cell, the mutated nucleic acid of the invention, wherein the animal expresses a human amyloid precursor protein or fragment thereof which encodes an amino acid other than lysine at codon 670 and/or an amino acid other than methionine at codon 671.

Mullan, col. 4, lines 35-40. Elan argues that the Mullan reference does not show all of the limitations of the Elan claims and does not enable the transgenic animal it describes. Elan stresses the uncertainty and difficulty of producing a transgenic animal, and argues that although Mullan foresaw a transgenic mouse and presented a compilation of known methods of gene transfer, the reference does not teach or suggest which method might succeed in creating the desired mutated mouse. Mayo in turn stresses the comprehensiveness of the Mullan disclosure, and that Elan indeed eventually succeeded with one of the methods mentioned by Mullan, using the Swedish gene discovered by Mullan and a mouse species recited by Mullan.

The Mullan reference summarizes the various known gene transfer techniques, with citations to scientific literature describing these techniques. The following extract is illustrative:

> One approach to creating transgenic animals is to target a mutation to the desired gene by homologous recombination in an embryonic stem (ES) cell line in vitro followed by microinjection of the modified ES cell line into a host blastocyst and subsequent incubation in a foster mother (see Frohman and Martin, *Cell* (1989) 56:145). Alternatively, the technique of microinjection of the mutated gene, or a portion thereof, into a onecell embryo followed by incubation in a foster mother can be used. Certain possibilities for the general use of transgenic animals, particularly transgenic animals that express a wildtype APP fragment, are disclosed in Wirak et al., the *EMBO Journal*, 10(2) 289296 (1991); Schilling et al., *Gene* 98(2) 225230 (1991); Quon, et al. (1991) *Nature* 352:239; Wirak, et al. (1991) *Science* 253:323; and Kawabata, et al. (1991) *Nature* 354:476. Alternatively, viral vectors, *e.g.*, Adenoassociated virus, can be used to deliver the mutated gene to the stem cell. In addition, such viral vectors can be used to deliver the mutated gene to a developed animal and then used to screen (Mendelson et al., *Virology* 166:154165; Wondisford et al. (1988) *Molec. Endocrinol.* 2:3239 (1988)).

Mullan, col. 11, line 58 to col. 12, line 11. Mullan states that site-directed mutagenesis can also be used, preferably so as to produce the desired mutation. The Mullan reference also names various known cloning vectors for creation of transgenic animals, and states that the vector is "selected based on the size of the desired insert and the ability to produce stable chromosome integration." The Mullan reference contains additional information, with citations to scientific articles and textbooks, proposing how vectors "can be constructed," the transgene "can be injected," and like statements.

Elan stresses that Mullan does not suggest which, if any, of the methods and vectors he cites might reasonably be predicted to succeed in producing a mouse operatively harboring the Swedish mutation. As explained in *Enzo Biochem*, 188 F.3d at 1372, "an enablement determination is made retrospectively, *i.e.*, by looking back to the filing date of the patent application and determining whether undue experimentation would have been required to make and use the claimed invention at that time." Thus the enablement of the Mullan and Elan mice would be determined separately.

The issue is not whether the Mullan teachings are an accurate compilation of the state of the scientific

art at that time, and they are not challenged on that ground. The issue is whether his teachings enabled a person of ordinary

Page 1378

skill, without undue experimentation, to produce the desired transgenic mouse. The district court did not directly address the question of enablement, which was not the subject of the summary judgment motion.

Thus we remand for determination by the district court, upon consideration of relevant evidence and upon application of the law to the facts of this case, of whether the Mullan reference enabled persons of ordinary skill in the field of the invention to make the desired mutated mouse without undue experimentation.

II

This appeal was directed to the summary judgment that was granted on the ground of anticipation. Mayo's other defenses of invalidity, and the question of infringement, were not reached by the district court. Mayo's argument that the claims are invalid under §103 and/or §112, particularly if construed to have the breadth that Elan ascribes to them in order to reach the Mayo mouse, and any other issues properly raised, remain for consideration on remand.

REVERSED AND REMANDED

- End of Case -

ISSN 1526-8535

226 USPQ 619
In re Donohue
U.S. Court of Appeals Federal Circuit

No. 85-868

Decided July 3, 1985

766 F2d 531

Headnotes

PATENTS

[1] Prior adjudication -- Applications for patent (▶ 56.05)

Patent Office properly declined to make formal res judicata rejection of patent application that, by including affidavit not submitted in earlier-rejected application, presented new issue of material fact.

[2] Patentability -- Anticipation -- Publications -- In general (▶ 51.2271)

Disclosure of claimed invention in printed publication will not suffice as prior art if it was not enabling, but invention disclosed in publication need not actually have been made in order to satisfy enablement requirement.

[3] Patentability -- Anticipation -- Combining references (▶ 51.205)

Anticipation rejection was proper based on additional references which were not relied upon for suggestion or motivation to combine teachings to meet claim limitations, but were rather used to show that claimed subject matter, as disclosed in single reference that discloses every element claimed, was in public's possession.

Particular Patents

Particular patents -- Acids

Donohue, Tetramethylbiphenylcarboxylic Acids and Derivatives Thereof, rejection of claims 1, 2, 5, 6, 7, 25, and 28, *affirmed*.

Case History and Disposition

Appeal from Patent and Trademark Office Board of Appeals.

Application for patent of John A. Donohue, Serial No. 263,900, filed May 15, 1981, division of Serial No. 60,909, filed July 26, 1979, continuation-in-part of Serial No. 622,249, filed Oct. 15, 1975, continuation-in-part of Serial No. 517,506, filed Oct. 24, 1974. From rejection of claims 1, 5, 6, 7, 25, and 28, applicant appeals. Affirmed.

See also 207 USPQ 196.

Attorneys

William Magidson, Chicago, Ill., for appellant.

Harris A. Pitlick, Associate Solicitor (Joseph F. Nakamura, Solicitor, and John W. Dewhirst, Associate Solicitor, on the brief) for Patent Office.

Judge

Before Markey, Chief Judge, Baldwin, Circuit Judge, and Miller, * Senior Circuit Judge.

* Judge Miller assumed senior status effective June 6, 1985.

Opinion Text

Opinion By:

Miller, Senior Circuit Judge.

This is an appeal from the decision of the U.S. Patent and Trademark Office ("PTO") Board of Appeals ("Board") sustaining the final rejection of appellant's claims [1] 1, 2, 5, 6, 7, 25, and 28. We affirm.

[1] In application Serial No. 263,900, filed May 15, 1981, for Tetramethylbiphenylcarboxylic Acids and Derivatives Thereof, which is a division of Serial No. 60,909, filed July 26, 1979, and a continuation of Serial No. 622,649, filed October 15, 1975, which is a continuation-in-part of Serial No. 517,506, filed October 24, 1974.

BACKGROUND

The subject matter of this appeal was previously before this court's predecessor in *In re Donohue,* 632 F.2d 123, 207 USPQ 196 (CCPA 1980) *("Donohue I").* [2] There is no need to discuss the details of that opinion; however, a summary of the pertinent facts is appropriate for a full understanding of the issues before us.

[2] *Donohue I* involved application No. 622,649. *See* note 1, *supra.*

The present invention relates to 2,2',6,6'-tetramethylbiphenyl-4,4'-dicarboxylic acid compounds which are suitable for producing polymers used to form shaped objects, such as film, fibers, or molded parts. Claim 1, which is the sole independent claim on appeal, is illustrative:

> 2,2',6,6'-tetramethylbiphenyl-4,4'-dicarboxylic acid compound comprising said acid, an acyl halide derivative thereof, or a simple ester thereof.

The PTO has rejected all the appealed claims under 35 U.S.C. § 102(b) "as anticipated by Nomura [et al.], optionally in view of Lincoln and Walker [et al.]."

Nomura et al. ("Nomura") [3] discloses twelve 2,2',6,6'-tetramethylbiphenyls ("TMBP") which are 4,4'-disubstituted with NH_2, NMe_2, OH, OMe, Cl, Br, I, CO_2H, CO_2Me, CN, NO_2, or H substituents. Methods of preparing all these compounds, except those disubstituted with CO_2H or CO_2Me, are set forth in Nomura. Nomura's disclosure of how to make 4,4'-dinitrile (or dicyano) TMBP is particularly significant, because Lincoln [4] and Wagner et al. ("Wagner") [5] teach, generally, the preparation of carboxylic acids from nitriles by hydrolysis.

[3] Yujiro Nomura and Yoshito Takeuchi, "Substituent Effects in Aromatic Proton Nuclear Magnetic Resonance Spectra. Part VI. [$2H_6$] Benzene-induced Solvent Shifts in 4,4'-Disubstituted 2,2',6,6'-Tetramethylbiphenyls and Related Compounds," *J. Chem. Soc'y (B),* 956-60 (1970).

[4] U.S. Patent No. 3,876,691, issued April 8, 1975, on application No. 351,696, filed April 16, 1973, for a "Process for the Hydrolysis of Nitriles."

[5] Wagner et al., *Synthetic Organic Chemistry* 412-15 (John Wiley & Sons, N.Y., N.Y.) (1965).

In *Donohue I,* a majority of the Court of Customs and Patent Appeals ("CCPA") *affirmed* the PTO's rejection of appealed claims 1, 5, 6, and 7 [6] under 35 U.S.C. § 102(b). *Id.* at 127, 207 USPQ at 200. The basis for the rejection was, as it is here, Nomura with reference to Lincoln and Wagner. *Id.* at 126, 207 USPQ at 199.

[6] Claim 1 in *Donohue I* differs from claim 1 of the present appeal only in that the latter includes the limitation "comprising said acid, an acyl halide derivative thereof, or a simple ester thereof." Claims 5, 6, and 7 of *Donohue I* specify the same dependent features as in the presently-appealed claims of the same number.

A minority of the CCPA voted to reverse the PTO's decision, because they concluded it was uncertain from the text of Nomura that the dicarboxylic acid TMBP and dimethyl ester TMBP were ever prepared. *Id.* at 129, 207 USPQ at 201. Accordingly, Nomura's disclosure was, in the minority's view, no more than a mere naming of the claimed compounds which is insufficient to constitute an enabling disclosure. *Id.* at 129, 207 USPQ at 201.

After *Donohue I,* the presently-appealed application was filed. During prosecution before the PTO, appellant submitted an affidavit under 37 C.F.R. § 1.132 executed by Dr. Ellis K. Fields ("Fields affidavit"). In this affidavit, Dr. Fields states that he wrote to Dr. Yoshito Takeuchi, one of the authors of Nomura, to ask whether the disclosed dicarboxylic acid TMBP or dimethyl ester TMBP compounds were ever synthesized, as indicated in Nomura. Dr. Takeuchi responded by stating that these compounds were not synthesized, and Dr. Fields submitted his affidavit to that effect.

Despite the Fields affidavit, the examiner finally rejected the claims, and an appeal to the board was filed. The board *affirmed* the rejection of the claims on the grounds stated *supra,* holding that it was bound by *Donohue I.* As to the Fields affidavit, the board held that whether the authors of Nomura actually prepared the claimed compounds is not "material or relevant"; rather, the key factor in evaluating the adequacy of a reference's dis

Page 621

closure was deemed to be whether that disclosure would have been enabling, and the board determined that the CCPA had decided that question with respect to Nomura.

ANALYSIS

[1] Appellant has made a record different from that in *Donohue I* by submitting the Fields affidavit. This new record presents a new issue of patentability with respect to whether the previously sustained anticipation rejection can still be maintained. In view of this new issue, the PTO properly declined to make a formal *res judicata* rejection and addressed the question of whether the Fields affidavit overcomes the rejection of the claims based on Nomura. *See In re Ackermann,* 444 F.2d 1172, 1176, 170 USPQ 340, 343 (CCPA 1971); *In re Russell,* 439 F.2d 1228, 1230, 169 USPQ 426, 48 (CCPA 1971); *In re Herr,* 377 F.2d 610, 611, 153 USPQ 548, 549 (CCPA 1967).

Appellant argues that the Fields affidavit, which states that the authors of Nomura did not make the disclosed dicarboxylic acid TMBP and dimethyl ester TMBP compounds, overcomes the PTO's rejection. It is urged that *Donohue I* and *In re Samour,* 571 F.2d 559, 197 USPQ 1 (CCPA 1978), require, *inter alia,* that a 35 U.S.C. § 102(b) rejection based on a primary reference disclosing a claimed compound in conjunction with one or more references which teach how to make that compound, should be sustained only if the claimed compound was actually made. We disagree.

[2] It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it. [7] *In re Sasse,* 629 F.2d 675, 681, 207 USPQ 107, 111 (CCPA 1980); *In re Samour,* 571 F.2d at 562, 197 USPQ at 4; *see also Reading & Bates Construction Co. v. Baker Energy Resources Corp.,* 748 F.2d 64, 651-52, 223 USPQ 1168, 1173 (Fed.Cir. 1984). Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. *See In re LeGrice,* 301 F.2d at 939, 133 USPQ at 373-74. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling. *In re Borst,* 345 F.2d 851, 855, 45 USPQ 554, 557 (CCPA 1965), cert. denied, 382 U.S. 973, 148 USPQ 771 (1966.) It is not, however, necessary that an invention disclosed in a publication shall have actually been made in order to satisfy the enablement requirement.

[7] This rule is based on the "described in a printed publication" language in 35 U.S.C. § 102(b). *See In re LeGrice,* 301 F.2d 929, 936, 133 USPQ 365, 371 (CCPA 1962).

In re Wiggins, 488 F.2d 538, 179 USPQ 421 (CCPA 1973) and *In re Sheppard,* 339 F.2d 238, 144

USPQ 42 (CCPA 1964), do not support a contrary view. In those cases, the references were deemed insufficient, because they stated that attempts to prepare the claimed compounds were unsuccessful. Such failures by those skilled in the art (having possession of the information disclosed by the publication) are strong evidence that the disclosure of the publication was nonenabling. By contrast, the fact that the author of a pubication did not attempt to make his disclosed invention does not indicate one way or the other whether the publication would have been enabling.

Although *In re Samour* and *Donohue I* mention that the claimed invention in each case was apparently produced in conjunction with the anticipatory reference, this is a far cry from proclaiming that such production is required to meet the enablement requirement. *In re Samour,* in fact, states:

> [W]hether or not [the claimed invention] has been made previously is not essential to a determination that a method of preparing it would have been known by, or would have been obvious to, one of ordinary skill in the art.

571 F.2d at 563 n.6, 197 USPQ at 4 n.6. Therefore, the statements in *In re Samour* and *Donohue I* that the claimed invention was made previously serve to point out the absence of any strong evidence of nonenablement as in *Wiggins* and *Sheppard. See In re Donohue,* 642 F.2d at 126 n.6, 207 USPQ at 199 n.6.

At oral argument, appellant also challenged the correctness of the CCPA's holding in *In re Samour* and *Donohue I* that several references can be used together to support an anticipation rejection. However, we are bound by the CCPA's decision in those cases. *South Corp. v. United States,* 690 F.2d 1368, 1370-71, 215 USPQ 657, 658 (Fed.Cir. 1982). At the same time, we have no difficulty with the rejections made in *In re Samour* and *Donohue I.*

[3] It is elementary that an anticipation rejection requires a showing that each limitation of a claim must be found in a single reference, practice, or device. *E.g., Dalman v. Kimberly-Clark Corp.,* 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed.Cir. 1983), cert. denied, 104 S.Ct. 1284, 224 USPQ 520 (1984). The anticipation rejection used here, as in *In re Samour* and *Donohue I,* is not

Page 622

inconsistent with this rule. *See In re Marshall,* 578 F.2d 301, 304, 198 USPQ 344, 346 (CCPA 1978). The additional references utilized in this case (viz., Lincoln and Wagner) are not relief upon for suggestion or motivation to combine teachings to meet the claim limitations, as in rejections under 35 U.S.C. §103. *In re Samour,* 571 F.2d at 563, 197 USPQ at 4-5. Such reliance would be pointless, because Nomura alone discloses every element claimed. The purpose of citing Lincoln and Wagner is, instead, to show that the claimed subject matter, as disclosed in Nomura, was in the public's possession. *Id.* Therefore, the anticipation rejection based on Nomura, Lincoln, and Wagner is proper. [8]

[8] *Compare Studiengesellschaft Kohle, M.B.H. v. Dart Industries, Inc.,* 726 F.2d 724, 220 USPQ 841 (Fed.Cir. 1984) (recognized exception occasionally permitting use of additional references in anticipation rejections but holding exception did not apply).

Appellant also argues that the references fail to teach the solubility characteristics and melting point range set forth in dependent claims 25 and 28, respectively. [9] However, where, as here, the dicarboxylic acid TMBP and dimethyl ester TMBP of Nomura are identical to the claimed invention, the properties of Nomura's compounds are inherently the same as those of the claimed invention in the absence of proof to the contrary. *See In re Best,* 562 F.2d 1252, 1255, 195 USPQ 430, 433-34 (CCPA 1977).

[9] Claims 25 and 28 read as follows:

> 25. The acid of Claim 2, said acid being soluble in ether and N-Methyl-2-pyrrolidone.
>
> 28. the dimethyl ester of Claim 7, having a melting point of 128-129°C.

In view of the foregoing, the board's decision is *affirmed.*

AFFIRMED

- End of Case -

ISSN 1526-8535

Source: USPQ, 1st Series (1929 - 1986) > U.S. Court of Appeals, Federal Circuit > Paperless Accounting, Inc. Rapid Transit System, 231 USPQ 649 (Fed. Cir. 1986)

231 USPQ 649
Paperless Accounting, Inc. v. Bay Area Rapid Transit System
U.S. Court of Appeals Federal Circuit

Nos. 86-597 and 86-756

Decided October 28, 1986

804 F2d 659

Headnotes

PATENTS

[1] Patentability -- In general (▶ 51.01)

Pleading and practice in courts -- Motions -- For summary judgment -- For dismissal (▶ 53.6333)

Federal district court erred in granting summary judgment of patent invalidity based upon its holding that patentee's filing of continuation-in-part application constituted admission of insufficiency of disclosure as matter of law, since there was no final rejection on insufficiency of disclosure from which to appeal, no abandonment of claims, and no outstanding rejection in which patentee could have acquiesced.

[2] Patentability -- Anticipation -- In general (▶ 51.201)

Patents -- Foreign (▶ 51.2215)

Foreign publication which is is substantially same as parent application that had been found insufficient to place claimed invention in possession of public is also insufficient to anticipate such claim under 35 USC 102(b).

Particular Patents

Particular patents -- Fare System

3,609,300, Halpern, Automatic Fare Charging System, holding of invalidity *reversed*.

Case History and Disposition

Page 649

Appeal from District Court for the Northern District of California, Vukasin, J.

Action by Paperless Accounting, Inc., against Bay Area Rapid Transit System, for patent infringement. From decision granting defendant's motion for summary judgment, plaintiff appeals. Reversed and *remanded*.

Attorneys

William D. Hall and Hall, Myers & Rose, both of Potomac, Md. (Maurice U. Cahn, on the brief, and Jack L. Slobodin and Cartwright, Sucherman & Slobodin, both of San Francisco, Calif., of counsel) for appellant.

Clyde C. Greco, Jr., and Wiles, Circuit & Tremblay, both of La Jolla, Calif. (Jon B. Miller, and Wiles, Circuit & Tremblay, both of La Jolla, Calif., and Roger W. Erickson, and Owen, Wickersham & Erickson,

both of San Francisco, Calif., on the brief) for appellee.

Judge

Before Markey, Chief Judge, and Baldwin and Newman, Circuit Judges.

Opinion Text

Opinion By:

Newman, Circuit Judge.

Paperless Accounting, Inc. ("Paperless") appeals the judgment of the United States District Court for the Northern District of California, holding U.S. Patent No. 3,609,300 ("the '300 patent") invalid in terms of 35 U.S.C. §102(b), and granting the motion of Bay Area Rapid Transit System ("BART") for summary judgment of dismissal of Paperless' Action for patent infringement. *Paperless Accounting, Inc. v. Bay Area Rapid Transit System,* No. C-83-5833 JPV, slip op. (N.D. Cal. Sept. 13, 1985), aff'd on reconsideration (Dec. 3, 1985).

The summary judgment is *reversed* and the case is *remanded* for further proceedings.

Background

The '300 patent was issued to John W. Halpern on September 28, 1971, and is assigned to Paperless. The specification and claims describe an automatic passenger fare charging system. On entry to a transit system, the claimed machine electronically reads data stored on a ticket, and generates a signal on the ticket relating to the entrance's location. Upon exit the machine electronically compares the exit and entry locations, calculates the fare, and compares the result with the price paid for the ticket. The machine tells the ticket holder what is due, and credits any overpayment. The specification describes the details of the construction and operation of the system, and the claims are directed to the machine. The detailed scope of the claims is not here pertinent.

The summary judgment turns on certain facts of patent prosecution before the Patent and Trademark Office ("Office").

Page 650

The first or "parent" United States patent application, Serial NO. 659,196 ("the '196 parent"), was filed on April 16, 1957 by inventor Halpern, then of Stockholm, Sweden, *pro se,* with claims directed to the machine, the feeding mechanism, and the ticket. Halpern illustrated his system in part with drawings that included block diagrams, of which Figure 5 as filed is representative:

Tabular, graphic, or textual material set at this point is not available. Please consult hard copy or call BNA at 1-800-372-1033.

In the first Office action on the merits, dated April 12, 1958, all of the claims were rejected by the examiner as based on an incomplete and insufficient disclosure. The examiner advised the applicant as to how this rejection might be overcome, instructing the applicant to describe the circuits of the components that were shown only by block diagrams, and suggesting that reference could be made to "existing publications and patents which show known circuits." The examiner cautioned the applicant to avoid the addition of new matter. The examiner also made several formal requirements relating to the filing of ribboned and sealed application papers and to the form of the drawings, and made other rejections not here pertinent.

In his response filed September 24, 1958 Mr. Halpern submitted extensive amendments to the specification in which he referred to three electronics publications, submitted new Figures 1-21, and replaced the original claims with new claims 22-38.

In the second Office action, dated September 4, 1959, the examiner stated that the amendment to the specification included "a large amount of new matter" and required cancellation of specific parts of the amendment. The examiner treated the new figures as proposed sketches, accepted new Figures 1-13 as correcting the original figures, and stated that new Figures 14-21 appeared to contain new matter and would not be admissible. The examiner rejected new claims 22-38 as being based on an

insufficient disclosure, and stated: "Applicant is again advised that in order to supply the needed disclosure to cure the defects set out in the last Office action, he must convincingly demonstrate that the elements are well known and obtainable on the open market or that there is a full disclosure thereof in patents or other publications". The examiner advised Mr. Halpern that "final determination in respect to the disclosure will be made in the next action."

In response, filed March 7, 1960, Mr. Halpern presented extensive argument that there was support for certain parts of the previous amendment in the original specification, and provided additional material, that he described as "explanatory", for insertion into the specification. Mr. Halpern canceled other parts of the previous amendment which he described as disclosing "other new aspects or further development of the proposed invention." Mr. Halpern cited a publication that he stated showed "all essential parts" of the circuit in Figure 27 (numbered Figure 14 in Halpern's first amendment).

In the third Office action, dated August 25, 1961, the examiner did not repeat the rejection for inadequate or insufficient disclosure. Only claim 36 was rejected as "drawn to new matter [without] basis for the claim in the original disclosure." The examiner stated that the application claimed three distinct inventions and required the applicant to elect which claims he wished to pursue in this application. The examiner stated that Mr. Halpern's amendment of March 4 [sic], 1960 had not been entered pending this election, and that if the claims directed to the machine were elected they would be subject to rejection on the ground of being an old combination as shown by Lorenz in U.S. Patent 2,591,448, a newly cited reference.

In response filed February 20, 1962 Mr. Halpern elected the claims to the ticket, claims 37 and 38, and rewrote these claims as new claims 39 and 40. Mr. Halpern canceled claim 36, and *argued* the patentability of claims 22-35 in view of the Lorenz reference.

In the fourth Office action dated May 14, 1962, the examiner held that claims 22-35 stood "*withdrawn* from further consideration . . . as being for nonelected inventions", and that "the discussion [in the] amendment concerning claims 22-35 is not being considered." The examiner rejected elected claims 39 and 40 as unpatentable in view of Knutsen's U.S. Patent 2,508,953, and as indefinite for failing to state positively that there are recesses containing recording tracks in the ticket.

In his next response, filed July 30, 1962, Mr. Halpern was represented by counsel, who amended claims 39 and 40 to the ticket and

Page 651

presented arguments as to the patentability of this subject matter. These two claims were "finally rejected" in the fifth Office action, August 27, 1962, as being unpatentable in view of the Knutsen reference. In an amendment filed Sept. 14, 1962 Halpern's counsel re*argued* the ticket claims, and stated: "Claims 22-35 are retained pending filing of a divisional application."

A notice of appeal was filed, and on February 27, 1963 a continuation-in-part application, Serial No. 261,529 ("the '529 c-i-p"), was filed containing the non-elected claims 22-35 directed to the machine. Claim 36, which had been rejected as drawn to new matter and canceled in the '196 parent, was not included in the '529 c-i-p.

The appeal of the final rejection of claims 39 and 40 in the '196 parent was not pursued, and that application became abandoned when the appeal was dismissed for failure to file a brief.

The specification of the '529 c-i-p included substantially all the material in the amendments filed September 30, 1958 and March 14, 1960 in the '196 parent. After further prosecution including refiling, the '529 c-i-p led to the '300 patent here at issue.

More than one year before the filing date of the '529 c-i-p, the following foreign patents issued to Mr. Halpern: French Patent No. 1,199,266 on December 11, 1959; British Patent No. 857,658 on January 4, 1961; and Canadian Patent NO. 613,866 on February 7, 1961. The parties agree that these foreign patents correspond substantially to the specification and drawings of the '196 parent as filed in the U.S. on April 16, 1957.

These facts are not in dispute, although their legal significance is. Thus the basis on which the district court decided the question was amenable to summary determination. Fed.R.Civ.P. 56.

Analysis

A.

The district court granted BART's motion for summary judgment of patent invalidity based on Halpern's intervening foreign patent publications, apparently holding these foreign patents to bar the '300 patent in terms of 35 U.S.C. §102(b). [1] This holding was based on the court's conclusion that the claims of the '300 patent are not entitled to the filing date of the United States '196 parent application.

---

[1] A person shall be entitled to a patent unless --

> (b) the invention was patented or described in a printed publication in . . . a foreign country . . . more than one year prior to the date of the application for patent in the United States. . . .

The district court held that Halpern admitted that the '196 parent application's disclosure was insufficient because he filed the '529 c-i-p application and abandoned the '196 parent without appeal. The district court, according to its opinion, based its decision solely on this conclusion of acquiescence, the court stating that "Halpern . . . failed to prosecute his appeal after the Patent and Trademark Office examiner's final rejection of his claims. Instead, he filed a Continuation-In-Part application containing additional disclosures. . . . [H]e has thus acquiesced to the examiner's decision and is thereby bound." Slip op. at 2-3 (Dec. 3, 1985)(citing *Litton Systems, Inc. v. Whirlpool Corp.,* 728 F.2d 1423, 1440, 221 USPQ 97, 107 (Fed.Cir. 1984)).

The court's conclusion was based on an erroneous understanding of the prosecution history. There was no rejection for insufficient disclosure at the time the '529 c-i-p was filed and the '196 parent was abandoned. That rejection had been *withdrawn*, as a matter of standard procedure. The applicable rule is stated in the Manual of Patent Examining Procedure (MPEP), an operating manual that "describe[s] procedures on which the public can rely." *Patlex Corp. v. Mossinghoff,* 758 F.2d 594, 606, 225 USPQ 243, 252, modified, 771 F.2d 480, 226 USPQ 985 (Fed.Cir. 1985); *In re Kaghan,* 387 F.2d 398, 401, 156 USPQ 130, 132 (CCPA 1967). The rule for the pertinent period was as follows:

707.07 (e) *Note all Outstanding Requirements*

> In taking up an amended case for action the examiner should note in every letter all the requirements outstanding against the case. Every point in the prior action of an examiner which is still applicable must be repeated or referred to, to prevent the implied waiver of the *requirement.* [emphasis in original]

The examiner's rejection of the '196 parent for insufficient disclosure was not "repeated or referred to" in the third or subsequent Office actions. The MPEP is not permissive in this requirement. It is notable that only claim 36 was rejected in the third Office action as based on new matter. The '196 disclosure as it then stood, in accordance with MPEP §707.07(e), was no longer rejected as insufficient.

The district court referred to Halpern's "fail[ure] to prosecute his appeal after the examiner's final rejection of his claims." Had Halpern prosecuted the appeal of the final rejection of claims 39 and 40, as he was entitled to do but did not, the issue of sufficiency of disclosure could not have been raised in such appeal. It was not at issue, because that ground

Page 652

of rejection had not been continued by the examiner. As stated in *Ex parte Martin,* 104 USPQ 124, 128 (Supr. Exmr. 1952):

> When an examiner fails to mention a rejection in his final action, it has been dropped by the examiner and needs no further response by the applicant. On appeal, only those grounds of rejection which have been made in the final rejection and commented upon in the examiner's answer to brief are considered by the Board. All rejections previously made and not continued in the final rejection are considered as *withdrawn*. It is not necessary for the examiner to make any specific statement to that effect.

Since the question of sufficiency of disclosure was not a basis for the final rejection, it could not have been appealed. Failure to pursue the appeal of the rejection of claims 39 and 40 on other grounds is of no significance to this issue.

There was no outstanding rejection on insufficient disclosure in which the applicant could have acquiesced, either when he declined to pursue the appeal of claims 39 and 40 in the '196 parent, or when he filed the '529 c-i-p. In *Litton,* by contrast, the parent patent application had been finally rejected for insufficient disclosure and the rejection was not appealed. In the case before us no claims were ever finally rejected for insufficient disclosure, and no rejection was appealable on this ground.

The district court stated that "[t]he subsequent filing of the Continuation-In-Part application exhibited both acquiescence in and compliance with the examiner's position on the inadequacy of the patent application's disclosure." Slip op. at 3 (Dec. 3, 1985). The filing of a continuation-in-part, in and of itself, is not an admission of the correctness of a rejection. Law and policy liberally authorize the filing of c-i-p applications for a number of reasons, whether to enlarge the disclosure to include new technological information, thereby providing the public with knowledge of recent developments or improvements; or to enable more extensive prosecution or improved draftsmanship of specification or claims; or to provide a vehicle for prosecution of non-elected claims.

In those cases where a continuation-in-part application contains claims which depend upon an enlarged disclosure for support, that must of course be considered when it is required to establish dates of compliance with 35 U.S.C. §112. But the mere filing of a continuation-in-part with additional matter or revised claims is not of itself an admission that the matter is "new" or that the original application was legally insufficient to support the claims. *See State Industries, Inc. v. A.O. Smith Corp.,* 751 F.2d 1226, 1233 n.*, 224 USPQ 418 , 422 n.1 (Fed.Cir. 1985) and cases cited therein; *see also Foseco International Ltd. v. Fireline, Inc.,,* 607 F.Supp. 1537, 1563, 226 USPQ 33, 35 (N.D. Ohio 1984).

BART also advised the district court that Paperless was not entitled to any date earlier than February 27, 1963 for any of the claims in the '300 patent because Halpern had "abandoned" the claims to the machine in the '196 parent application. This was an incorrect statement of law. Halpern's election to proceed first with his claims to the ticket, reserving the right to proceed with the other claims in a separate application, is a routine step in patent prosecution. *See* 35 U.S.C. §121; MPEP §§802.01, 803.

[1] Since there was no final rejection on insufficiency of disclosure from which to appeal, no abandonment of claims, and no outstanding rejection in which Halpern could have acquiesced, the district court erred in holding that Halpern admitted as a matter of law that his disclosure was insufficient. The grant of summary judgment on this basis was legal error, and is *reversed.*

B.

Paperless asks us to hold that the claims of the '300 patent are entitled to the filing date of the '196 parent application, thus predating the intervening foreign references. The issue of support for claims in the specification as required by §112 is a question of law, *Atlas Powder Co. v. E.I. du Pont de Nemours & Co.,* 750 F.2d 1569, 1573, 224 USPQ 409, 411 (Fed.Cir. 1984); *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co.,* 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed.Cir. 1984), but it is dependent on underlying factual and legal findings which have not here been made. The district court did not analyze Halpern's '196 disclosure, as filed or as amended, with respect to the claims of the '300 patent, basing its summary judgment solely on the conclusion of acquiescence. Although the parties *argued* this issue on appeal, it is inappropriate for our decision *ab initio.* As we remand to the district court, we restate the issue, in view of the conflicting views of the parties not only as to the answer, but as to the question.

Whether the intervening foreign patent references are 35 U.S.C. §102(b) bars against any or all of the claims of the '300 patent depends on the content and dates of the foreign references and the priority dates to which each of the '300 patent claims is entitled. *See In re Ahlbrecht,* 435 F.2d 908, 911-12, 168 USPQ 293, 296 (CCPA 1971); *see also Litton,* 728 F.2d at 1438, 221 USPQ at 106. If a claim of the '300 patent is adequately supported by the

Page 653

disclosure in the '196 parent, the intervening references are of no effect.

A patent applicant need not include in the specification that which is already known to and available to the public. *In re Howarth,* 654 F.2d 103, 105, 210 USPQ 689, 691-92 (CCPA 1981); *In re Lange,* 644 F.2d 856, 863, 209 USPQ 288, 294 (CCPA 1981). Thus, in examining the '196 parent, the examiner

had invited Halpern to refer to published circuits and commercially available items that performed the function of Halpern's boxes. Such added subject matter, to the extent that is not "new matter", does not deprive the applicant of the original filing date. *See Litton,* 728 F.2d at 1438, 221 USPQ at 106; *In re Wright,* 343 F.2d 761, 767, 145 USPQ 182, 188 (CCPA 1965).

If there are claims in the '300 patent which are not entitled to the '196 filing date because they depend for patentability on "new matter" appearing for the first time in the '529 c-i-p, as to those claims Halpern must meet the requirements of patentability as if the foreign patents were any adverse reference.

Because the foreign patents correspond substantially to the disclosure of the '196 parent, as both parties averred (we observe that they are not identical in all respects), it is pertinent to consider this fact if the '196 parent is held insufficient as to any claim of the '300 patent. As this court held in *In re Donohue,* 766 F.2d 531, 226 USPQ 619 (Fed.Cir. 1985), a §102(b) reference "must sufficiently describe the claimed invention to have placed the public in possession of it." *Id.* at 533, 226 USPQ at 621 (citing *In re Samour,* 571 F.2d 559, 562, 197 USPQ 1, 4 (CCPA 1978)). The court observed in *Donohue* that "even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it was not enabling." *Id.* (citing *In re Borst,* 345 F.2d 851, 855, 145 USPQ 554, 557 (CCPA 1965), cert. denied, 382 U.S. 973, 148 USPQ 771 (1966) ("the disclosure must be such as will give possession of the invention to the person of ordinary skill")). *See also Reading & Bates Construction Co. v. Baker Energy Resources Corp.,* 748 F.2d 645, 651-52, 223 USPQ 1168, 1173 (Fed.Cir. 1984); *Preemption Devices, Inc. v. Minnesota Mining & Manufacturing Co.,* 732 F.2d 903, 906, 221 USPQ 841, 843 (Fed.Cir. 1984). The basis for this rule is found in the description requirement of §102(b). *Donohue,* 766 F.2d at 533 n.7, 226 USPQ at 621 n.7 (citation omitted). If the disclosure of the '196 parent application is insufficient to place the claimed invention in the possession of the public, then its British, French, and Canadian counterparts are also insufficient to do so.

[2] Thus, if any claim of the '300 patent is determined to be limited to the filing date of the '529 c-i-p on the basis that the disclosure of the '196 parent is insufficient to support such claim, a corresponding foreign publication that is substantially the same is also insufficient to anticipate such claim under §102(b). The correct role of the foreign publication is such case is as a reference under §103. *Reading & Bates,* 748 F.2d at 652, 223 USPQ at 1173. Such analysis has not been made, and is not before us on appeal.

REVERSED AND REMANDED

- End of Case -

ISSN 1526-8535

Source: USPQ, 2d Series (1986 - Present) > U.S. District Courts, Massachusetts > United States Filter Corp. v 53 USPQ2d 1071 (D. Mass. 1999)

53 USPQ2d 1071
United States Filter Corp. v. Ionics Inc.
U.S. District Court District of Massachusetts

No. 98-10541-REK

Decided October 8, 1999

68 FSupp2d 48

Headnotes

JUDICIAL PRACTICE AND PROCEDURE

[1] Procedure -- Judicial review -- Standard of review -- Patents (► 410.4607.09)

U.S. Court of Appeals for the Federal Circuit, hearing appeal from U.S. Patent and Trademark Office under 35 U.S.C. Section 141, must review findings of patent validity under "substantial evidence" standard enunciated in Administrative Procedure Act; however, that requirement does not apply to federal district court reviewing PTO's findings pursuant to 35 U.S.C. Section 145.

[2] Procedure -- Judicial review -- Standard of review -- Patents (► 410.4607.09)

Federal district court considering evidence that was before patent examiner, or that was presumed to be before patent examiner, during prosecution of reissue application owes deference to examiner's finding with regard to that patent's validity; however, if new evidence not considered by examiner is relied on, then court considering it is not faced with having to disagree with U.S. Patent and Trademark Office, or with deferring to its judgment or with taking its expertise into account.

[3] Procedure -- Judicial review -- Standard of review -- Patents (► 410.4607.09)

Federal district court's "nonexpert judicial factfinding" will be reviewed on appeal by the U.S. Court of Appeals for the Federal Circuit for "clear error," that is, under stricter court/court standard, rather than more deferential court/agency "substantial evidence" standard.

[4] Patentability/Validity -- In general (► 115.01)

JUDICIAL PRACTICE AND PROCEDURE

Procedure -- Judicial review -- Standard of review -- Patents (► 410.4607.09)

Federal district court deciding question of patent validity on motion for summary judgment must review admissible evidence, giving deference only to those findings made by patent examiner with regard to evidence before examiner or presumed to be before examiner, and in applying that evidence to defendant's legal theories for patent invalidation, court must determine whether sufficient admissible evidence is in record to support jury finding of patent invalidity by clear and convincing evidence.

[5] Patentability/Validity -- Anticipation -- Identity of elements (► 115.0704)

JUDICIAL PRACTICE AND PROCEDURE

Procedure -- Summary judgment -- Patents (► 410.3303)

Patentee may defeat allegation of anticipation by choosing one element that exists in every

allegedly anticipated claim, and showing how no single prior art reference anticipates that element; to defeat motion for summary judgment, patentee need only show genuine dispute of material fact as to whether that one claim element "reads-on" prior art, but patentee could also show that issue should be decided as matter of law in its favor by demonstrating that no genuine dispute of material fact exists as to possibility that, by clear and convincing evidence, prior art anticipates claim element at issue.

[6] Patentability/Validity -- Anticipation -- In general (► 115.0701)

Deference is owed patent examiner's finding of patent validity in considering infringement defendant's allegation of anticipation, since prior art cited by defendant was before examiner during prosecution of reissue patent in suit, and since examiner is presumed to have considered that prior art.

[7] Patentability/Validity -- Anticipation -- Identity of elements (► 115.0704)

Asserted claims of patent for electrodeionization apparatus using anion and cation exchange resin beads are not anticipated by prior art publication, since claims require use of ion exchange resin beads having "substantially uniform size," since admissions and testimony, and passages in article itself, indicate that person of ordinary skill in art would not be able to determine, from reading article, whether ion exchange beads described therein were accurately separated by size within range permitted by patent, and since defendant has proffered no evidence that would allow finding that article is enabling as required by precedent.

[8] Patentability/Validity -- Anticipation -- Identity of elements (► 115.0704)

Asserted claims of patent for electrodeionization (EDI) apparatus using anion and cation exchange resin beads are not anticipated by prior art advertisements, even though advertisements disclose ion exchange resin beads of "substantially uniform size" required by claims, since advertisements do not specify which process for purifying liquid will be improved by advertised resin beads, and since advertisements thus do not disclose use of "substantially uniform size" resin beads in EDI apparatus as described by patent; neither plaintiffs' experimentation with these resin beads, nor presence of beads in EDI apparatus, renders patent invalid.

[9] Practice and procedure in Patent and Trademark Office -- Reissue -- Same invention (► 110.1305)

Practice and procedure in Patent and Trademark Office -- Reissue -- Broader claims sought (► 110.1313)

First step in applying "recapture rule" of 35 U.S.C. Section 251 is to determine whether and in what aspect reissue claims are broader than original patent claims; second step is to determine whether broader aspects of reissued claims relate to surrendered subject matter and, if they do, to determine, through examination of original patent's prosecution history, whether broader claims are attempt to impermissibly recapture limitations surrendered in order to overcome prior art rejection.

[10] Practice and procedure in Patent and Trademark Office -- Reissue -- Same invention (► 110.1305)

Practice and procedure in Patent and Trademark Office -- Reissue -- Broader claims sought (► 110.1313)

Term "original" in 35 U.S.C. Section 251, which states in relevant part that no reissued patent "shall be granted enlarging the scope of the

Page 1073

claims of the original patent," means patent from which new, *corrected* patent issued, and does not include all applications, abandoned and continued, and all issued patents related in any way to patent from which *corrected* patent issued; court engaging in recapture analysis therefore must look only to prosecution history of patent from which *corrected* patent issued in order to determine whether claim language at issue was surrendered, during prosecution of that patent, to overcome

some prior art rejection, which would then render corresponding reissue claims invalid.

[11] Practice and procedure in Patent and Trademark Office -- Reissue -- Same invention (► 110.1305)

Practice and procedure in Patent and Trademark Office -- Reissue -- Broader claims sought (► 110.1313)

Substitution of word "secured" in claims of reissue patent for word "bonded" in original patent for electrodeionization (EDI) apparatus did not violate "recapture rule" of 35 U.S.C. Section 251, even though "secured" is broader than "bonded," since no changes made in application for original patent to overcome prior art involved word "bonded," and therefore nothing surrendered during prosecution of that patent relates to "bonded," and since change from "bonded" to "secured" thus cannot be impermissible recapture.

[12] Practice and procedure in Patent and Trademark Office -- Reissue -- In general (► 110.1301)

Infringement -- Defenses -- Fraud or unclean hands (► 120.1111)

Plaintiffs' failure to comply with 37 C.F.R. Section 1.172 through inadvertent mis-naming of assignee cannot rise to level of inequitable conduct that would require invalidation of reissue patent in suit, since, whether or not plaintiffs' error was material, it is undisputed that plaintiffs did not intend to deceive or defraud U.S. Patent and Trademark Office.

Particular Patents

Particular patents -- Chemical -- Water purification

Re. 35,741 (of 5,154,809), Oren, Giuffrida, Ciaccio, and Ganzi, process for purifying water, patent held not invalid on motion for summary judgment.

Case History and Disposition

Action by United States Filter Corp., U.S. Filter/Ionpure Inc., IP Holding Co., Millipore Corp., and Millipore Investment Holdings Ltd. against Ionics Inc. for patent infringement. On defendant's motion for summary judgment of patent invalidity, and on plaintiffs' cross-motion for summary adjudication of validity issue. Plaintiffs' motion granted.

Attorneys

Jerome P. Facher, William F. Lee, Wayne M. Kennard, Mark D. Selwyn, Christine A. Maglione, Dimitry S. Herman, Beth E. Turetsky, Wayne L. Stoner, and Peter M. Dichiara, of Hale & Dorr, Boston, Mass.; Elizabeth Olivier, of United States Filter Corp., Palm Desert, Calif., for plaintiff.

Steven M. Bauer and John J. Cotter of Testa, Hurwitz & Thibeault, Boston; Jeffrey R. Martin of Burns & Levinson, Boston; Stephen Korn, Watertown, Mass.; Anthony J. Fitzpatrick, Michael R. Gottfried, and Dennis D. Allegretti of Duane, Morris & Heckscher, Boston, for defendant.

Opinion Text

Opinion By:

Keeton, J.

I. Pending Matters

Pending for decision, after a three-day evidentiary hearing on September 14, 15, and 16, 1999, are the following motions:

(1) Defendant's Motion for Summary Judgment of Invalidity of the Patent In Suit (Docket No. 92, filed December 21, 1998) with supporting memoranda (Docket Nos. 93, 121, 129, 146, 153, 180, 211). Plaintiffs have filed numerous oppositions and replied (Docket Nos. 100, 110, 111, 125, 150, 201).

(2) At the beginning and at the end of a three-day evidentiary hearing on September 14, 15, and 16, 1999, plaintiffs moved for Partial Summary Adjudication with regard to all three of defendant's claims of patent invalidity: anticipation, impermissible recapture of surrendered subject matter, and an erroneously-designated assent of assignee of a patent for which a reissue application was pending. *See* Hearing Transcript, Volume I, at 18-19 (Docket No. 224) and Hearing Transcript, Volume III, at 40 (Docket No. 226). The substance of and the written support for plaintiffs' cross-motion for summary adjudication on these claims of defendant appear in their oppositions to Defendant's Motion for Summary Judgment. *See* Docket Nos. 110, 111, 125, 150, 201.

II. Procedural Background

This case involves plaintiffs' alleged cause of action against defendant for patent infringement.

Page 1074

In response to plaintiffs' claims, defendant argues that plaintiffs' patent, U.S. Patent Reissue No. 35,741 (" '741 Reissue Patent"), is invalid for three reasons: (1) lack of novelty (*i.e.,* anticipation), (2) unlawful recapture of surrendered subject matter in a reissued patent, and (3) procedural errors in the filing of the reissue application, namely misidentifying the assignee of U.S. Patent 5,154,809 (" '809 Patent") from which the '741 Reissue patent reissued. As noted above, the court held an evidentiary hearing over the period of three days, September 14-16, 1999. One purpose of the hearing was to determine whether triable jury issues exist with regard to the invalidity of the '741 Reissue patent.

At the close of the three-day hearing, defendant renewed its motion for summary judgment as to the invalidity of the '741 Reissue patent. Also, plaintiffs cross-moved for partial summary adjudication that as a matter of law no genuine dispute of material fact exists as to any of the defendant's three defenses.

> "So at the end of day, your Honor, [plaintiffs] would suggest that the facts are undisputed as to the third motion, and the appropriate action we would request would be to have the court enter a partial summary adjudication that the assent of assignee filed with a technically incorrect identification of one of the assignees has no effect on the validity of the patent.

We also think at the end, your Honor, the facts will support a determination by the Court that, as a matter of law, the original application had this 'bond' language and therefore there has been no recapturing.

And as to the prior art, there are, for sure, disputed, issues of fact, but on the record and Ionics' [defendant's] contention, we would suggest the Court enter partial summary adjudication that none of the references Ionics relies upon anticipates and renders on their own invalid any of the claims." Hearing Transcript, Vol. I at 18-19.

III. Factual Background

This case arises from plaintiffs' development of an electrodeionization apparatus ("EDI") that became the subject matter of the '741 Reissue Patent. The '741 Reissue Patent, which issued on March 10, 1998, is a reissue of the '809 Patent, which issued on October 13, 1992.

Generally, the '741 Reissue Patent teaches a liquid purification process that depends on electrical forces to remove impurities, such as ionic salts, from a liquid such as water. In the EDI apparatus that is disclosed in the '741 Reissue Patent, a liquid to be purified flows through ion depleting compartments out of which ions are drawn through a permeable membrane into ion concentrating compartments by virtue of a polar electrical field. The ion depletion compartments contain mixed cation (negatively charged) and anion (positively charged) exchange resin beads in order to facilitate the migration of impurities such as ionic salts from the ion depletion compartments to the ion concentrating compartments; the ion concentrating compartments may contain ion exchange resin beads, if desired, depending upon the mode of electrodeionization.

The '741 Reissue Patent teaches an EDI apparatus in which the depletion compartments are made of a series of subcompartments formed by (1) an anion permeable membrane and a cation permeable membrane that extend along the length of the depletion compartments and (2) a pair of "ribs" that extends across the width of the depletion compartments. The '741 Reissue Patent specification describes these subcompartments as enabling an "efficient mixing of the liquid and the beads therein"

by constraining the movement of solid ion exchange material and thereby effecting a more thorough and cost effective purification process. *See* '741 Reissue Patent, col. 5, lines 1-4, 44-50 (Pl.'s Ex. 4; Def.s Ex. 501). The specification further explains that by controlling the dimensions of the subcompartments in the way that the '741 Reissue Patent describes in detail, *see id.* at col. 4, lines 50-67, the desired liquid purity can be attained with relatively less energy requirements, even over long time periods. *See id.* at col. 5, lines 50-55.

In the EDI apparatus taught by the '741 Reissue Patent, the ion exchange resin beads that are used in the ion depletion compartments and sometimes in the ion concentrating compartments are described, throughout the text of the patent, as being of "substantially uniform size." *See, e.g.,* '741 Reissue Patent at p. 116,296 ("Abstract"); col. 1, line 30 and col. 2, line 27 ("Background of the Invention"); col. 2, lines 57-63 ("Summary of the Invention"); col. 4, lines 22-23, 30, col. 7, lines 46-47, col. 9, line 52 ("Description of Specific Embodiments"); col. 12, line 43 (Claim 1, and thus also Claims 2-8 that are dependent on Claim 1); col. 14, line 37 (Claim 11, and thus also Claims 12-18 that are dependent on Claim 11); col. 15, line 26, (Claim 19, and thus also Claim 20 that is dependent on Claim 19); col. 15, line 46

Page 1075

(Claim 21, and thus also Claims 22-30 that are dependent on Claim 21).

The '741 Reissue Patent's specification explains "substantially uniform size" as "mean [ing] that 90% of the beads are within += 10% of the mean bead size and that the relative average size of one ionic form of resin beads to a second ionic form of resin beads in a mixture of resin beads is at least 0.8." *See* '741 Reissue Patent, col. 2, lines 57-63. This feature of the '741 Reissue patent -- ion exchange resin beads of substantially uniform size -- is at the core of defendant's contention that claims 1-8 and 11-30 of the '741 Reissue Patent are invalid as anticipated by prior art that allegedly discloses ion exchange resin beads of substantially uniform size in EDI apparatuses.

IV. Standard of Review

A. At Summary Judgment

Summary judgment should be granted only if the court, viewing the evidence in the light most favorable to the non-moving party, determines that no genuine dispute of material fact exists. *See* Fed.R.Civ.P. 56. The movant has the "initial responsibility of informing the district court of the basis for its motion, and identifying those portions" of the record showing the absence of a genuine dispute of material fact. *Celotex Corp.* v. *Catrett,* 477 U.S. 317, 323 (1986). A factual question is material if a reasonable jury could return a verdict for the non-moving party based at least in part on its determination of the factual question. *See Anderson* v. *Liberty Lobby, Inc.,* 477 U.S. 242, 248 (1986). In a patent validity action such as this one, the burden on the party moving for judgment as a matter of law as to patent invalidity is even heavier than in other contexts generally because the patent is presumed valid. *See* 35 U.S.C. Section 282 (1994).

B. Regarding A District Court's Review of the Patent and Trademark Office's Finding of Validity

One who challenges a patent's validity must prove invalidity by clear and convincing evidence. *See Finnigan Corp.* v. *International Trade Com'n* 180 F.3d 1354, 1365 [52 USPQ2d 1001] (Fed.Cir. 1999). Thus, in order to satisfy its burden at summary judgment, the defendant-movant must show that no genuine dispute of material fact exists that would enable a reasonable jury to find by clear and convincing evidence that the patent is valid. *See Anderson,* 477 U.S. at 255; *Oney* v. *Ratliff,* 182 F.3d 893, 895 [51 USPQ2d 1700] (Fed.Cir. 1999); *Rockwell Int'l Corp.* v. *U.S. et al,* 147 F.3d 1358, 1361 [47 USPQ2d 1027] (Fed.Cir. 1998).

[1] Defendant argues that the Supreme Court's decision in *Dickinson* v. *Zurko,* 119 S.Ct. 1816 [50 USPQ2d 1930] (1999), requires that this court, the United States District Court for the District of Massachusetts, review the Patent and Trademark Office's (PTO's) findings of validity under the standard of review enunciated by section 706 of the Administrative Procedure Act, 5 U.S.C. Section 706. If defendants were correct in their interpretation of *Zurko,* this court would be permitted to set aside the PTO's findings if they were unsupported by "substantial evidence." *See* 5 U.S.C. Section 706 (2)(E).

But the discussion in *Zurko* does not focus upon the standard of review applicable to the procedural

posture of the present case, which is the review by a United States District Court of the PTO's findings under 35 U.S.C. Section 145. The procedural posture of the present case follows a path that Justice Breyer, in the majority opinion in *Zurko,* says "might well lead to Federal Circuit court/court review" on appeal. *See Zurko,* 118 S.Ct. at 1824. Instead, *Zurko* focused upon the standard of review for the Federal Circuit when it hears an appeal from the PTO under 35 U.S.C. Section 141, a path that Justice Breyer distinguishes as leading to a review by the Federal Circuit of the PTO's findings under a "court/agency" standard. *See Zurko,* 118 S.Ct. at 1817, 1824 (comparing appellate court review of findings of fact made by a district court judge under the stricter "clearly erroneous" standard with appellate court review of findings of fact made by the PTO under the less strict "substantial evidence" standard).

[2] I do not accept defendant's argument that *Zurko* has changed the standard of review that this court must apply in reviewing the PTO's finding of a valid patent. The law is clear, and *Zurko* has not changed it, that when considering evidence that was before the patent officer or that was presumed to be before the patent officer during the prosecution of the '741 Reissue patent, I owe deference to the finding made by the patent officer with regard to that patent's validity. *See American Hoist & Derrick Co. v. Sowa & Sons,* 725 F.2d 1350, 1359-60 [220 USPQ 763] (1984), *cert. denied* 469 U.S. 821 (1984). In contrast, " [w]hen new evidence touching validity of the patent not considered by the PTO is relied on, the tribunal considering it is not faced with having to disagree with the PTO or with deferring to

Page 1076

its judgment or with taking its expertise into account." *Id.* at 1360.

[3] Regardless of the deference owed to the patent officer, however, I must consider all admissible evidence in light of the clear and convincing standard by which patents must be proved invalid. *See id.* The point that *Zurko* clarifies, but that does not affect the standard under which this court reviews the evidence, is the point that this court's "nonexpert judicial factfinding" will be reviewed on appeal by the Federal Circuit for "clear error" -- that is, under the stricter court/court standard rather than the more deferential court/agency "substantial evidence" standard -- ensuring that the new evidence submitted in this patent proceeding that was not considered by the PTO will be closely scrutinized by an expert body. *See Zurko,* 119 S.Ct. at 1824.

[4] Therefore, I conclude that I must review the admissible evidence proffered to this court during the three-day hearing on September 14-16, 1999, giving deference only to those findings made by the patent examiner with regard to the evidence before him or presumed to be before him, and, when applying all the admissible evidence to defendant's three legal theories for patent invalidation -- (1) anticipation, (2) impermissible recapture, and (2) the effect of procedural defects -- I must determine whether sufficient admissible evidence is before me to support a jury finding that by clear and convincing evidence the '741 Reissue patent is invalid. *See id.* (outlining precisely this procedure).

V. Invalidity Analysis

A. Anticipation

In defendant's papers and during the three-day evidentiary hearing, defendant challenged the validity of the '741 Reissue Patent on the basis that it was anticipated by prior art. The instances of prior art defendant points to are as follows: (1) a 1964 article by Gerald J. Gittens and Ronald E. Watts entitled "Some Experimental Studies of Electrodeionisation Through Resin Packed Beds" ("Gittens and Watts article"); (2) a 1971 paper by V.D. Grebenyuk, T.Z. Sotskova, and N.P. Gnusin entitled "Effect of Electric Current on Electrodialyser Compartments Filled With a Mixed Bed of Variable-Composition Ion-Exchange Resins" ("Grebenyuk article"); and (3) four brochures printed by Dow Chemical Company entitled "Dowex Monosphere Resins," "Unprecedented Bead Size Uniformity Provides Near-Perfect Separation In Condensate Polishers," "The New Dowex Monosphere TG," and "With High-Performance Dowex Monosphere Resins" (collectively "Dow publications").

The parties do not dispute that the Gittens and Watts article and the Dow publications were before the patent officer during the prosecution of the '741 Reissue patent. These references are listed on the face of the '741 Reissue Patent "Other Publications." *See* '741 Reissue Patent at pp. 116,298-299. Also, the parties do not dispute that a 1973 article by T.Z. Sotskova *et al.* entitled "The Mechanism of the Conduction of Electric Current Through a Mixed Resin Bed" (the "Sotskova article") was before the patent officer during the prosecution of the '741 Reissue Patent. It, too, is listed on the face of the

'741 Reissue Patent under "Other Publications." *See id.* at 116,299. The parties do dispute the factual issue as to whether the Sotskova article discloses the EDI apparatus in the Grebenyuk article that allegedly anticipates the patent-in-suit. Such disclosure, as matter of law, would render the Grebenyuk article less pertinent or merely cumulative with the Sotskova article that was before the patent officer during prosecution. *See Engel Indus., Inc.* v. *Lockformer Co.,* 946 F.2d 1528, 1533 [20 USPQ2d 1300] (Fed.Cir. 1991); *see also* discussion *infra,* at Part V. A. 3, "The Person of Ordinary Skill in the Art," and Part V. 4. A. 4(d) "The Grebenyuk Article and the Sotskova Article." The Grebenyuk article was not listed under "Other References" that were considered by the patent officer during the prosecution of the '741 Reissue Patent. *1. Applicable Law*

A determination of anticipation involves two steps: "first is construing the claim, a question of law for the court, followed by [. . .] a comparison of the construed claim to the prior art." *Key Pharmaceuticals* v. *Hercon Laboratories Corp.,* 161 F.3d 709, 714 [48 USPQ2d 1911] (Fed.Cir. 1998). "The comparison process involves fact-finding, and is for the fact-finder in the first instance." *Id.* On a motion for summary judgment, however, as on a motion for judgment as a matter of law during a jury trial, it is for the court to decide whether a genuine dispute of material fact exists as to the comparison process.

Invalidity by anticipation requires that the party arguing for invalidity prove by clear and convincing evidence "that each and every limitation of the claimed invention be disclosed in a single prior art reference." *In re Paulsen,* 30 F.3d 1475, 1478-79 [31 USPQ2d 1671]

Page 1077

(Fed.Cir. 1994) (citations omitted). This means that if a prior art reference lacks any claimed element, then as a matter of law a decisionmaker (whether in the patent office or in a court) cannot find anticipation. *See Kloster Speedsteel AB* v. *Crucible, Inc.,* 793 F.2d 1565, 1571 [230 USPQ 81] (Fed.Cir. 1986), *cert. denied,* 497 U.S. 1034 (1987). "In addition, the reference must be enabling and describe the applicant's claimed invention sufficiently to have placed it in possession of a person of ordinary skill in the field of the invention." *In re Paulsen,* 30 F.3d at 1478-79.

Defendant asks this court, when considering whether the '741 Reissue Patent is invalid because it is anticipated by prior art, to look solely to the PTO's "Reasons for Allowance" (*see* Def.'s Ex. 505 at p. 117,118) to explain how (and if) the '741 Reissue Patent differs from the prior art. In the "Reasons for Allowance" statement, the patent examiner wrote:

> The claims are allowable because none of the prior art of record fairly discloses or renders obvious the claimed electrodeionization method and apparatus, the ion depleting compartment comprising a mixture of anion and cation exchange resin beads having a substantially uniform size positioned between an anion exchange membrane and a cation exchange membrane.

Id. In asking the court to look solely to the PTO's "Reasons for Allowance," defendant commits three errors. First, the defendant interprets the patent examiner's statement to mean that the only reason the '741 Reissue Patent issued was because it contains "substantially uniformed size" ion exchange resin beads. The plain meaning of this document, were I to consider only this document for purposes of determining whether or not the prior art anticipates the present patent-in-suit, is not what defendants want it to be. The patent examiner, in his statement, does not highlight the disputed "substantially uniform size" phrase alone, as do defendants. Instead, the patent examiner states that it is the " *claimed electrodeionization method* and *apparatus,* [which includes] the ion depleting compartment . . ." (*id*) (emphasis added) that distinguishes the invention from prior art. The patent examiner's statement contains no indication that it is the "substantially uniform size" feature, and that feature alone, that makes the invention patentable.

Defendant's second error is related to the first. By asking this court to consider the "substantially uniform size" feature, and only that feature for the purposes of the anticipation analysis, defendants implicitly invite this court to assume that each and every limitation of the '741 Reissue Patent (except for the disputed "substantially uniformed size" ion exchange resin beads feature) is disclosed in each prior art reference. Thus defendant does not offer its suggested claim construction for the terms it asks the court to assume are disclosed by the prior art. Defendant does not even offer a construction of the terms plaintiffs contend are novel to the '741 Reissue Patent, *e.g.,* "substantially uniform size," "subcompartment," "spacer," "ribs." If this court were to accept defendant's invitation, it would be abdicating its role (assigned to it by the Supreme Court and the United States Court of Appeals for the Federal Circuit in patent infringement cases and patent invalidity determinations) of construing claims and applying that construction to each prior art reference, element by element, claim by claim. *See,*

e.g., Scripps Clinic & Research Foundation v. *Genentech, Inc.,* 927 F.2d 1565, 1576 [18 USPQ2d 1001] (Fed.Cir. 1991) (stating (1) that " [i]nvalidity for anticipation requires that all of the elements and limitations of the claim are found within a single prior art reference;" and (2) that it is required that no difference exist "between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the field of the invention") (citations omitted). The defendant suggests a short cut, but in so doing, defendant asks the court to commit legal error.

Lastly, should the defendant be asking the court to compare the '741 Reissue Patent with the prior art only in terms of whether each prior art discloses the use of "substantially uniform size" ion exchange resin beads in an EDI apparatus, defendant effectively would be asking this court to assume that each prior art reference is not significantly different from the other for the purposes of an anticipation analysis. This not only runs counter to common sense but also is contrary to law. I therefore reject defendant's suggestions and continue with the anticipation analyses as prescribed by the United States Court of Appeals for the Federal Circuit. *See Key Pharmaceuticals,* 161 F.3d at 714. *2. Claim Construction (a) The Prescribed Approach*

In *Markman,* the Supreme Court established that the determination of the scope of a patent is "exclusively within the province of the court." *Markman* v. *Westview Instruments, Inc.,* 517 U.S. 370, 372 [38 USPQ2d 1461] (1996).

Page 1078

In discharging this responsibility, a court looks first to the words of the claim itself. *See Vitronics Corp.* v. *Conceptronic, Inc.,* 90 F.3d 1576, 1582 [39 USPQ2d 1573] (1st Cir. 1996). Generally, the words of the claim are given their ordinary and accustomed meaning. *See Renishaw PLC* v. *Marposs Societa per Azioni,* 158 F.3d 1243, 1249 [48 USPQ2d 1117] (Fed.Cir. 1998). If some assertion is made that the words have a meaning other than their plain meaning, the court may look to the patent specification or prosecution history to see whether the patentee has in one of those places stated a clear definition. *See id.* Thus, "a technical term used in a patent document is interpreted as having the meaning that it would be given by persons experienced in the field of the invention, unless it is apparent from the patent and the prosecution history that the inventor used the term with a different meaning." *Hoechst Celanese Corp. v. BP Chems. Ltd.* , 78 F.3d 1575, 1578 [38 USPQ2d 1126] (Fed.Cir. 1996).

Although a court may look to the specifications to resolve an ambiguous term or to find that the patentee has defined some term in a manner other than the ordinary meaning, *see Vitronics* , 90 F.3d at 1582, it is not appropriate to give effect to a patentee's attempt to impose upon the claim, through the specification, some limit that is not included in the claim itself. *See Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc.* , 34 F.3d 1048, 1054 [32 USPQ2d 1017]= (Fed.Cir. 1994) ("claims are not to be interpreted by adding limitations appearing only in the specification"); *In re Van Geuns* , 988 F.2d 1181, 1184 [26 USPQ2d 1057] (Fed.Cir. 1993) ("limitations are not to be read into the claims from the specification").

Finally, when construing claims, a court may look only to extrinsic evidence, *i.e.* , "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treaties [, . . .] in order to aid the court in coming to a correct conclusion as to the true meaning of the language employed in the patent." *Markman* , 52 F.3d at 980 (citations and quotations omitted). Significantly, " [e]xtrinsic evidence is to be used for the court's understanding of the patent, not for the purpose of varying or contradicting the terms of the claims." *Id.* at 981. The United States Court of Appeals for the Federal Circuit has consistently cautioned United States district courts against improper use of extrinsic evidence.

> The claims, specification, and file history, rather than extrinsic evidence, constitute the public record of the patentee's claim, a record on which the public is entitled to rely. In other words, competitors are entitled to review the public record, apply the established rules of the claim construction, ascertain the scope of the patentee's claimed invention and, thus, design around the claimed invention. Allowing the public record to be altered or changed by extrinsic evidence introduced at trial, such as expert testimony, would make this right meaningless.

Vitronics , 90 F.3d at 1583 (citations omitted). This rule of the proper use of extrinsic evidence during claim construction applies both to infringement analyses and invalidity determinations. *See In re Baxter Travenol Labs.* , 952 F.2d 388, 390 [21 USPQ2d 1281] (Fed.Cir. 1991); *Finnigan Corp.* , 180 F.3d at 1365. *(b) The Independent Claims*

Claim 1 is one of the four independent claims in the '741 Reissue Patent. Claims 2-4 expressly incorporate claim 1 with the language "The process of claim 1 wherein. . . ." ('741 Reissue Patent, Reissue Patent, col. 12, line 62; col. 13, lines 1, 16). Claims 5-8 expressly incorporate claim 4, which expressly incorporates claim 1, with the language "The process of claim 4 wherein. . . ." *See id.* at col. 12, lines 49, 51, 53, 59. Claim 15 expressly incorporates claim 1 with the language "The process of any one of claims 1, 2, 3, 4, 5, 6 or 8 . . . ." *Id.* at col. 15, line 7.

Claims 11, 19 and 21 are also independent claims. Claims 12-14 and 16 expressly incorporate claim 11, and claim 18 expressly incorporates claim 14, which incorporates claim 11. *See id.* at col. 14, lines 61, 63, 66 and col. 15, lines 10, 16. Claim 20 expressly incorporates claim 19. *See id.* at col. 15, line 29. claims 22-24 expressly incorporate claim 21. *See id.* at col. 16, lines 7, 10, 13. And claims 25-30 expressly incorporate claim 24, which expressly incorporates claim 21. *See id.* at col. 16, lines 24, 26, 28, 33, 36, 46.

All four independent claims contain the disputed phrase "substantially uniform size" to describe the ion exchange resin beads (both cation and anion) that are housed by the ion depleting compartments and sometimes by the ion concentrating compartments.

The independent claims, as they appear in the '741 Reissue Patent, are as follows:

> We claim: 1. A process for removing organic and ionic species from a liquid which comprises the steps of: a) providing an eletrodeionization apparatus which comprises:
>
> > i) a cathode compartment at a first end of the apparatus ii) an anode compartment at a second end of the apparatus opposite the first end iii) at least one ion concentrating compartment positioned adjacent to at least one ion depleting compartment, the ion depleting compartment comprising a mixture of anion exchange resin beads having a substantially uniform size and cation exchange resin beads having a substantially uniform size positioned between an anion exchange membrane and a cation exchange membrane, the ion depleting and ion concentrating compartments being positioned between the cathode compartment and the anode compartment, wherein the ion concentrating compartments are free of ion exchange resin,
>
> b) passing a first liquid through the ion depleting compartments, c) simultaneously passing a second liquid for accepting ions from the first liquid through the concentration compartments. d) applying an electrical voltage between an anode in the anode compartment and a cathode in the cathode compartment, and e) recovering the first liquid from the depleting compartment. . . . 11. A dual compartment construction adapted to remove ions from a liquid which comprises: an ion depletion compartment and an ion concentration compartment and an odd number of at least three ion permeable membranes. the ion permeable membranes comprising anion permeable membranes alternately positioned with respect to cation permeable membranes. each of the ion depletion compartments and each of the ion concentration compartments comprising a spacer and a plurality of ion depletion subcompartments and ion concentration subcompartments. the subcompartments being formed by a plurality of ribs extending along the length of each of the ion depletion compartments and the ion concentration compartments. each of the ion depletion subcompartments and the ion concentration subcompartments containing a mixture of anion exchange resin beads having a substantially uniform size and cation exchange resin beads of substantially uniform size. each of the ion depletion subcompartments and the ion concentration subcompartments formed by a plurality of ribs extending along the length of each of the ion depletion compartments, each of the subcompartments have a width defined by the distance between the ribs of between about 0.3 and 4 inches and a thickness between about 0.05 and 0.25 inches wherein the thickness of the subcompartment is defined by the distance between the anion permeable membrane and the cation permeable membrane each of the ion permeable membranes being secured to a spacer and the ribs within the spacer such that the anion permeable membrane and the cation permeable membrane are positioned alternatively along the length of the dual compartment a port for passing a first liquid to be purified through each ion depletion compartment. and a port for passing a second liquid for accepting ions from the first liquid through each ion concentration compartment. . . . 19. An electrodeionization apparatus comprising at least one ion concentrating compartment positioned adjacent to at least one ion depleting compartment, the ion depleting compartment comprising an ion exchange resin positioned, between an anion exchange membrane and a cation exchange membrane, wherein the ion exchange resin comprises a mixture of anion

exchange resin beads having a substantially uniform size and cation exchange resin beads having a substantially uniform size, and the ion concentrating compartment being free of ion exchange resin. . . . 21. A process for removing organic and ionic species from a liquid which comprises the steps of: a) providing an electrodeionization apparatus which comprises:

i) a cathode compartment at a first end of the apparatus, ii) an anode compartment at a second end of the apparatus opposite the first end, iii) at least one ion concentrating compartment positioned adjacent to at least one ion depleting compartment, the ion concentrating compartment and the ion depleting compartment comprising a mixture of anion exchange resin beads having a substantially uniform size and cation exchange resin beads having a substantially uniform size positioned between an anion exchange membrane

Page 1080

and a cation exchange membrane, the ion depleting and ion concentrating compartments being positioned between the cathode compartment and the anode compartment,

b) passing a first liquid through the ion depleting compartments, c) simultaneously passing a second liquid for accepting ions from the first liquid through the concentration compartments, d) applying an electrical voltage between an anode in the anode compartment and a cathode in the cathode compartment, and e) recovering the first liquid from the depleting compartment.

'741 Reissue Patent (bracketed portions indicating omitted words from the '809 Patent and italicized portions indicating changed words in the '741 Reissue Patent omitted). *(c) "Substantially Uniform Size" (i) The Parties' Positions*

In the parties' papers and during the evidentiary hearing, the primary dispute with regard to defendant's anticipation argument concerned whether the prior art discloses the use of "substantially uniform size" ion exchange resin beads in an ion depleting compartment of an EDT apparatus. Defendant chose to focus on this feature of the patent to the exclusion of all others, and, as I have said *supra* at Part V. A. 1., commits legal error in doing so. In fact, defendant has yet to argue that all of the other elements of the twenty-eight claims are anticipated by the prior art, an argument on which, as a matter of law, it would have to prevail in order to show that the prior art anticipates the patent-in-suit.

[5] In contrast, to defend against an allegation of anticipation, the plaintiffs need only show that not every element of every allegedly anticipated claim is disclosed by the prior art. *See Kloster* , 793 F.2d at 1571. They could do so by choosing one element of the patent that exists in every allegedly anticipated claim and show how none of the prior art anticipates that element. *See id* . To defeat defendant's motion for summary judgment, plaintiffs would only have to show a genuine dispute of material fact as to whether that one claim element "reads-on" the prior art. But if plaintiffs were to show that no genuine dispute of material fact exists as to the possibility that by clear and convincing evidence the prior art anticipates one claim element common to all the allegedly anticipated claims, then, as a matter of law, plaintiffs would have shown that this issue is one for court determination as matters of law are decided and is not for determination as a genuine dispute of material fact. Furthermore, they would have shown that it is decided as a matter of law in their favor.

Plaintiffs made just such an argument at the evidentiary hearing, stating that the court should decide as a matter of law that the patent-in-suit is not invalid for reasons of anticipation. They made the argument that no jury could reasonably find by clear and convincing evidence that the prior art discloses ion exchange resin beads of "substantially uniform size" in an EDI apparatus, an element which is common to all of the claims in the '741 Reissue Patent. Thus, plaintiff argues, as a matter of law, the prior art does not anticipate the '741 Reissue Patent. Plaintiffs also went beyond this argument to show how the prior art does not disclose many other claim elements of the patent-in-suit in an EDI apparatus (for example, "subcompartments," "spacers," and "ribs"), but, as those elements are not common to all of the allegedly anticipated claims, it is not necessary to focus on them now if a determination of the term "substantially uniform size" will be dispositive.) *(ii) Meaning of "Substantially Uniform Size"*

The '741 Reissue Patent specification explicitly defines "substantially uniform size" in column 2, line 57. It reads:

By the phrase "substantially uniform size" as applied to the anion resin beads or the cation

> resin beads as used herein means that 90% of the beads are within +10% of the mean bead size and that the relative average size of one ionic form of resin beads to a second ionic form of resin beads in a mixture of resin beads is at least 0.8.

'741 Reissue Patent, col. 2, line 57-64. Here, " [t]he specification acts as a dictionary when it expressly defines terms used in the claims . . ." *Vitronics,* 90 F.3d at 1582 *citing Markman,* 52 F.3d at 979.

The specification further clarifies the term "substantially uniform size" by suggesting "suitable ionic resin beads for use in the present invention," *i.e.,* ion exchange resin beads that would be "substantially uniform size." The specification suggests the Dowex Monosphere resin beads 550A and 650C for this purpose, stating that these commercially manufactured beads fit within the size parameters previously defined.

> The [Dowex Monosphere resin beads] 550A beads and 650C beads have 90% of the beads within += 10% of the mean bead size. The mean bead size of the 550A anionic resin beads is 550 micrometers while the 650C cationic resin beads has a mean bead size of 650 micrometers. The relative average size of the cationic resin beads to the anionic resin beads or vise [sic] versa should be at least about 80 percent of the other resin beads, preferably of substantially equal average size.

'741 Reissue Patent, col. 3 lines 43-50. This suggestion by the patent specification to use Dowex Monosphere 550A and 650C resin beads that perfectly fit within the numerical parameters set earlier supports those parameters as definitive of the phrase "substantially uniform size."

Neither defendant nor plaintiffs dispute this numerical definition of "substantially uniform size." At the hearing and in their papers, both accept that the specification speaks for itself and acts as a dictionary definition that provides no wiggle-room for going outside the numerical parameters.

I do not base my decision on an agreement between the parties, however. The reason is that the construction of the claim element is a matter of law for this court. Exercising this authority and responsibility for deciding this matter of law, I conclude that the specification is plain on its face and that no reason exists to depart from the definition that the patent provides. Thus, I conclude that "substantially uniform size" means that 90% (not substantially more and not substantially less) of the beads are within += 10% (not substantially more and not substantially less) of the mean bead size and that the relative average size of one ionic form of resin beads is at least (and not less than) 0.8.

The dispute regarding the phrase "substantially uniform size," however, does not center on precise numerical dimensions of bead size. Instead it concerns substantial *uniformity* of dimension. It concerns whether the substantial uniformity of the numerical parameters can be met by hydraulically separating ion resin beads or by sieving ion resin beads through various meshes.

Defendant argues and presented evidence purporting to show that sieving through appropriate meshes produces "substantially uniform size" ion exchange resin beads and thus the EDI apparatus disclosed in prior art that uses beads that were sieved through the appropriate mesh discloses the use of "substantially uniform size" ion exchange resin beads.

Plaintiffs argue and presented evidence that defendant's position is insupportable as a matter of law, and in the alternative that a genuine dispute of material fact exists as to whether sieving or hydraulic separation produces "substantially uniform size" ion exchange resin beads.

In evaluating this contrasting evidence, a court is not deciding an issue of claim construction. This decision is instead one to be made in the next step in the anticipation analysis -- the comparison of the claim as construed by the court to the pertinent elements of the prior art from the perspective of a person of ordinary skill in the art -- an analysis that requires consideration of evidence received by the court during the three-day hearing. *3. The Person of Ordinary Skill in the Art*

I accept as binding guidance for my adjudication a Federal Circuit ruling stating the legal test a court is to apply in determining characteristics of the person of ordinary skill in the art.

> The person of ordinary skill is a hypothetical person who is presumed to be aware of all the pertinent prior art. The actual inventor's skill is not determinative. Factors that may be considered in determining level of skill include: type of problems encountered in art; prior art solutions to those problems; rapidity with which innovations are made; sophistication of the technology; and educational level of active workers in the field.

Custom Accessories, Inc. v Jeffrey-Allen Indus., Inc., 807 F.2d 955, 962 [1 USPQ2d 1196] (Fed.Cir. 1986) (footnotes omitted). Applications of this legal test have confirmed that the test is a standard that envisions a person of relative sophistication within the field of the invention. *See In re Paulsen* , 30 F.3d 1475, 1481 [31 USPQ2d 1671] (person of ordinary skill in computer industry capable of "providing the circuitry necessary to make the device operable for use as a computer"); *Biogen, Inc. v. Amgen, Inc.,* 973 F.Supp. 39, 43 (D.Mass. 1987) (laboratory technician not person of ordinary skill in field of inducing nonhuman cells to produce human proteins because technicians not familiar with literature).

Defendant never presented to the court any evidence regarding the experience or level of education of persons in the field. Plaintiffs suggest in their papers that "[a]t the time the invention claimed in the '741 [Reissue] Patent was made, a person of ordinary skill in the art of the '741 [Reissue] Patent would have a B.S. or M.S. degree in a field providing a basis for understanding electrodeionization, such as physical chemistry or chemical engineering, and several years of experience in designing and working with water purification systems." Plaintiff's Proposed Additional or Substitute Findings and Conclusions, Docket No. 179 at 53. Considering the factors established in *Custom*

Page 1082

Accessories, I conclude that plaintiffs' suggestion is apt in part. The factors listed in *Custom Accessories* that plaintiffs do not suggest, but which I conclude are necessary in order to determine what one of ordinary skill in the art would understand from the prior art at issue, are that a person of ordinary skill in the art "is presumed to be aware of all the pertinent prior art . . . [and] the type of problems encountered in [the] art . . . [as well as] prior art solutions to those problems." *Custom Accessories,* 807 F.2d at 962. These Factors are important for the current invention because, by all parties accounts, the state of the art, in particular the commercialization of EDI systems, had changed in important ways since publication of the Gittens and Watts article, the Grebenyuk article and the Sotskova article. *See* Goldstein Declaration, Docket No. 194 at Para.10; Ganzi Declaration, Docket No. 192 at Para.6 Because of this, a person of ordinary skill in the art would have to be able to assess on a reasoned basis the difference between the prior art from decades past (such as the Gittens and Watts article) and the more recent prior art (such as the Dow publications) in light of the disputed novelty (*e.g.,* the contribution of "substantially uniform size" ion exchange resin beads) of the '741 Reissue Patent. *4. Comparing the Claim as Construed to the Prior Art (a) Preliminary Matters (i) Deference Owed The Patent Examiner Regarding Prior Art Considered During Patent Prosecution*

[6] As a preliminary matter, I reiterate that deference is owed the patent examiner's finding of validity (*i.e.,* that the prior art did not anticipate the patent in suit). The patent examiner had the Gittens and Watts article, the Dow publications and the Sotskova article before him during the prosecution of the '741 Reissue Patent (as is indicated by his initials next to the prior art citation, *see* Def.'s Ex. 13 ("Gittens and Watts article") and the list under "Other Refernces" on the '741 Reissue patent, *see* Def.'s Ex. 501 at 12.) Also, under applicable precedent, he is presumed to have considered the prior art as is required of an examiner in order to do the examiner's job properly. *See Molins PLC v. Textron, Inc.,* 48 F.3d 1172, 1186 [33 USPQ2d 1823] (Fed.Cir. 1995) ("The examiner initialed each reference, indicating his consideration of the same, and stated that he had considered all the prior art. Absent proof to the contrary, we assume that the examiner did consider the references."). *See also Markman,* 52 F.3d at 986 (stating that "patent examiners[ ] [are] quasi-judicial officials trained in the law and presumed to have some expertise in interpreting the [prior art] refernces and to be familiar from their work with the level of skill in the art") (bracketed phrase " [prior art]" in original) (citations and quotations omitted). Furthermore, " [w]here the patent in suit has been reissued under the provisions of 35 U.S.C. Sections 251 and 252, after consideration by the PTO of art not considered during the original prosecution [as is the case here with the '741 Reissue Patent, *see* '741 Reissue Patent at 1], the presumption of validity remains intact, and the challenger's burden of proof imposed by that presumption, as an evidentiary matter, is usually more difficult to sustain." *Kaufman Co., Inc. v. Lantech, Inc.,* 807 F.2d 970 [1 USPQ2d 1202] (Fed.Cir. 1986). *(ii) Relevancy Objections*

During the three-day hearing, defendant offered the testimony of Dr. Gerald J. Gittens, co-author of the Gittens and Watts article, for the purpose of "simply confirm [ing] for the court those portions of that publication which teach the use in an EDI apparatus of beads of substantially uniform size." Hearing Transcript, Vol. I at 20. Defendant also offered the testimony of Dr. Robert Kunin as "a pioneer resarcher in [the EDI field] . . . [who] has served with the manufacturers of the very beads we're talking about . . . [who can] confirm agaon for the court just what the Gittens and Watts patent discloses." *Id.*

Plaintiffs objected to Dr. Gitten's written and oral testimony (*see* Gittens Declaration, Docket No. 196) on relevance grounds. They also objected to paragraphs 15-46 of Dr. Kunin's written testimony (Kunin Declaration, Docket No. 195) and to his oral testimony in its entirety on relevance grounds. As with all evidentiary objections and motions during the three-day hearing, I took them under advisement with the case. I determine now, based on Dr. Kunin's professional accomplishments and experiences and his continuous research on ion exchange technology, ion exchange resin beads, water treatment and chemical processing, that Dr. Kunin's oral testimony and written declaration is relevant to what one of ordinary skill in the art would consider the prior art at issue to disclose. For the same reasons of professional accomplishments and experiences and continuous research on ion exchange technology, Dr. Thomas A. Davis's testimony (Davis Declaration, Docket No. 191) and Gary C. Ganzi (Ganzi Declaration,

Page 1083

Docket No. 192) are also relevant to what one of ordinary skill in the art would consider the prior art at issue to disclose. I therefore overrule defendant's objection to the admissibility of the testimony of Dr. Kunin, Dr. Davis and Mr. Canzi and consider all of them for the above stated purpose.

Whether Dr. Gittens' testimony is relevant, however, is less clear. In 1964, when Dr. Gittens co-authored the Gittens and Watts article, he was intimately involved with electrodeionization apparatuses. *See* Hearing Transcript, Vol. I at 122. He admitted, however, to leaving that particular field soon thereafter and moving to ceramics. *See id.* Twenty-five years passed before the application was filed for the '809 Patent, the patent from which the '741 Patent reissued. And thirty-one years passed before the application for the '741 Reissue Patent was filed that included the Gittens and Watts article as a prior art reference. By this time, nearly three decades later, Dr. Gittens was no longer working with EDI. *See id.* Dr. Gitten's testimony, which is uncontroverted, makes clear that in 1989 and again in 1996, he would not have been aware of the prior art references in the '809 Patent *(e.g.* , the Dowex Monosphere Resin Brochures, Mar. 1988) and he would not have been aware of the prior art references in the '741 Reissue Patent that were published after 1964 *(e.g.* , the Grebenyuk article and the Dow publications). *See id.* at 133. At one time Dr. Gittens may have been one who could qualify to give testimony about characteristics of one of ordinary skill in the art of electrodeionization apparatuses. But in 1989 he no longer qualifies. Thus, although he is the co-author of the Gittens and Watts article, and his testimony is relevant as to whether his article discloses an EDI apparatus using "substantially uniform size" beads to a person of ordinary skill in the art in *1964,* his testimony is not relevant as to whether a person of ordinary skill in the art in *1989* would understand his article to disclose the use of "substantially uniform size" beads in an EDI apparatus. In the analysis that follows, comparing the prior art to the '741 Reissue Patent, I consider Dr. Gittens' testimony for The purpose of illuminating his article, as its author, not as speaking directly to what a person of ordinary skill in the art in 1989 would consider it to disclose with regard to the patent-in-suit.

In addition to allowing Dr. Gittens' testimony in for that purpose, however, and because I recognize that a higher court might take a different position with regard to the relevance of his testimony, I have considered what decision I would make if I received his testimony into evidence without limitations, on the one hand, and with the above-stated limited purpose, on the other hand, and I have concluded that I would reach the same determination as to the validity of the '741 Reissue Patent under either of these different ways of proceeding.

Plaintiffs made other relevancy objections with regard to Defendant's Exhibits Nos. 519 ("Gittens and Watts article"), 520 ("Grebenyuk article"), 521-24 (the Dow publications), 525 (Dr. Kunin's Book "Ion Exchange Resins") and 526 ("Millipore Idea Disclosure") that were offered by defendant for the purpose of showing that the prior art anticipates the '741 Reissue Patent. I now determine that Defendant's Ex. Nos. 519-525 are relevant for this purpose, *i.e.* , that they have sufficient probative weight for this permissible purpose, and that their relevance is not outweighed by other factors to be considered by this court under Federal Rule of Evidence 403. In particular, although Dr. Kunin's book does not speak to the issue of anticipation before this court, it does provide background relied upon by Dr. Kunin in his assessment of what is disclosed by the prior art in relation to the patent-in-suit. As to Defendant's Exhibit No. 526, "Millipore Idea Disclosure," I do not consider it to be relevant to the issue of anticipation before me and therefore sustain plaintiffs' objection as to that exhibit. The use of that exhibit was to show that plaintiffs experimented with the Dowex Monosphere Resin beads in their development of electrodeionization apparatuses. That fact is not in serious dispute; plaintiffs disclose that fact to the world on the face of their patent, and to this court in particular in their papers and in their testimony. Furthermore, experimentation with commercially available products does not, by

itself, support a determination of anticipation as defendant contends. *See* my discussion of the Dow publications below at Part V. A. 4(c).

Defendant made relevancy objections as to Plaintiffs' Exhibits Nos. 18, (Ionics Interoffice Memo), 19 (British Patent 1,050,960), 20 (Gittens and Glueckauf article "The Application of Electrodialysis to Demineralisation" (1965)), 21 (Perry Chemical Engineers' Handbook at 8-8 (6th Ed. 1984), 22 (Leschonski article "Sieve Analysis, the Cinderella of Particle Size Analysis Methods?" (1979), 23 ("British Standard Specification for Test Sieves"), 24 (Otten and Fischer article, "Optical Size vs. Hand Screening" (1990)) and 25 ("Sotskova article") that were offered by plaintiffs for the purpose of showing that the prior art does not anticipate the '741 Reissue Patent. I now

Page 1084

determine that Plaintiffs' Exhibit Nos. 18-20 are not relevant for this purpose and therefore they are not admitted or considered by me in my determinations that follow. Furthermore, I determine that Plaintiffs' Exhibits Nos. 21-24 are only relevant in so far as they provide context to Dr. Kunin's opinion to which he testified that scientists will differ as to the accuracy of sieve analysis when controlling for particle size. *See, e.g.* , Hearing Transcript, Vol. II at 93. I do not admit them for the truth of the analyses they contain but only for the background they provide for Dr. Kunin's testimony when he says that he does not agree with scientists who declare, for example, that: "Finally, sieves are completely useless to measure particle size distribution of the so-called 'uniform particle size' resins . . . *(see* Pl.'s 24 at 338). I do consider Plaintiffs' Exhibit No. 25, the Sostkova article, to be relevant for the purpose of determining whether or not the prior art anticipates the '741 Reissue Patent. I therefore admit it over defendant's objections and consider it for that purpose in the analysis that follows. *(b) The Gittens and Watts Article*

Much of plaintiffs' cross-examination of Dr. Gittens and Dr. Kunin focused on the accuracy of hydraulic separation and sieving for the purpose of separating ion exchange resin beads into groups of "substantially uniform size." The Gittens and Watts article reports experiments that controlled for bead size by using these two separation techniques. *See* Gittens and Watts article, Def.'s Ex. 519 at pp. 4-5. (The Grebenyuk article (*see* Def.'s Ex. 520 at p. 987) also reports the use of sieving to control for bead size in EDI apparatuses.) One issue raised by the present motion is whether these techniques disclose the use of "substantially uniform size" beads as I have construed that term in the '741 Reissue Patent.

Under cross-examination, Dr. Gittens conceded that sieving in order to produce substantially uniform size ion exchange resin beads is a less than perfect process. *See* Hearing Transcript, Vol. I at 133, 145. He also explained that the experiments described in the Gittens and Watts article used sieving to control for the size of the ion exchange resin beads, but that he did not measure the beads as they were separated by the sieves; instead, he used a British Standard Specification for Test Sieves that recorded data on mesh sizes and indicated in percentage terms what the maximum variation in particle size could be after sieving through specified meshes. *See* Hearing Transcript, Vol I. at 140-143.

In the experiments reported in the Gittens and Watts article that used hydraulic separation to control for resin bead size, Dr. Gittens explained that he did make microscopic measurements to determine the success of the hydraulic separation (and the article confirms this, see Def.'s Ex. 519 at p. 5). Dr. Gittens then conceded that his article does not indicate the size of the sample measured, and he conceded that knowing the sample size would help to determine the accuracy of the measurements. *See* Hearing Transcript, Vol. II. at 27-28.

In addition to the admissions and testimony cited above, I note several passages in the Gittens and Watts article itself that compel me to conclude that no reasonable jury could find by clear and convincing evidence that to a person of ordinary skill in the art the Gittens and Watts article discloses the use of "substantially uniform size" ion exchange resin beads in an EDI apparatus such as the one taught by the '741 Reissue Patent.

First, on page 22, the Gittens and Watts article explicitly states that " [t]he parameters of importance in any discussion of electrodeionisation are the current density, solution concentration, flow rates, bead size and crosslinking . . . The present report is *not designed to deal fully with the bead size problem* and not at all with the resistance of beads; these problems are at present under a more thorough investigation." Def.'s Ex. 519 at 22 (emphasis added). To a person of ordinary skill in the art as I have defined that person, this caveat in the discussion of the article that reports the experiments'

results suggests that the procedures used did not adequately control for the size of ion exchange resin beads in order to make a determination of whether or not (or how) bead size has effects on the electrodeionization process.

Second, Figures 14 and 15 of the Gittens and Watts article, which are graphs that describe the "Dependence of [Current Efficiency] on Screening Range of Particle" and "Dependence of [Current Efficiency] on Particle Radius (r)", demonstrate that, according to the authors, the uniformity of size of ion exchange resins (as controlled by mesh ratios (Fig. 14) and by estimated particle size range (Fig. 15)) had no effect on the efficiency with which the EDI apparatus purified the water. *See id.* at 2 (defining "current efficiency" as "percentage of total current that is carried by the [sodium] ions"). *See also* Hearing Transcript, Vol. I at 135 (defining "current efficiency" as "the electric current that's making the ions move out of the depleting compartment." Dr. Gittens admitted as much under cross-examination,

Page 1085

See id. at 137-38 (admitting that "the one experiment [reported] that deals with particle size efficiency concludes that it has no effect [on current efficiency]"). *See also* Def. Ex. 519, "Gittens and Watts article" at p. 25 (stating that the authors' initial "hypothesis that particle size range has an effect on current efficiency is fallacious"). These figures and accompanying explanations demonstrate to a person of ordinary skill in the art that to the extent many sizes of ion exchange resin beads were used in the experiments and were accounted for, the experiments revealed no correlation between uniformity of bead size and the current efficiency of the EDI apparatus.

[7] On the record and evidence before me, I conclude that no reasonable jury could find by clear and convincing evidence that a person of ordinary skill in the art would understand the Gittens and Watts article to show or imply the use of "substantially uniform size" ion exchange resin beads in an EDI apparatus such as the one disclosed by the '741 Reissue Patent. A person of ordinary skill in the art would not be able to determine, by reading the Gittens and Watts article, whether the ion exchange beads were accurately separated by size within the range permitted by the patent or whether such a separation mattered at all for the results of the purification process. Furthermore, such a person would read that article and understand it to suggest that particle size was not a variable closely considered by the authors.

For all of these reasons, I uphold the patent officer's findings of no anticipation by the Gittens and Watts article. This finding does not consider all the other elements of claims 1-8 and 11-30 that may or may not be anticipated by the Gittens and Watts article. But because "substantially uniform size" ion exchange resin beads is an element in every allegedly anticipated claim, and because I have determined that that element is not anticipated by the Gittens and Watts article, I conclude as a matter of law that the Gittens and Watts article cannot be found to anticipate the '741 Reissue Patent. *See, e.g., Kloster Speedsteel AB,* 793 F.2d at 1571 ("the absence from the reference of any claimed element negates anticipation").

Finally, it is worth noting at this time, that no where in defendant's papers and never during the hearing did defendant attempt to compare all the other elements of the claims of the '741 Reissue Patent to the Gittens and Watts article as would be required for a finding of anticipation as matter of law. Thus, even if a higher court were to disagree with my determination today that no reasonable jury could find by clear and convincing evidence that "substantially uniform size" ion exchange resin beads as I have construed them are disclosed by the Gittens and Watts article, defendant has still not met its burden at summary judgment to prove that no genuine dispute of material fact exists as to the anticipation of all the other elements of all the twenty-eight disputed claims of the '741 Reissue Patent.

Furthermore, defendant has not made any argument or proffered any evidence that would allow me to find as a matter of law that the Gittens and Watts article is enabling as precedent requires. *See In re Paulsen,* 30 F.3d at 1479. An enabling disclosure is not "tossing out the mere germ of an idea" but the provision of "reasonable detail . . . in order to enable members of the public to understand and carry out the invention." *Genentech, Inc. v. Novo Nordisk A/S,* 108 F.3d 1361, 1366 [42 USPQ2d 1001] (Fed. Cir) *cert. denied* 118 S.Ct. 397 (1997). Based on the record before me, I cannot find as a matter of law that the patent officer made a mistake when it implicitly found (by issuing the '741 Patent over the prior art) that the Gittens and Watts article does not sufficiently describe the invention claimed in the '741 Reissue Patent, in particular its use of "substantially uniform size" ion exchange resin beads in ion-depleting compartments and sometimes in ion-concentrating compartments, "to have placed it

in possession of a person of ordinary skill in the field of the invention." *In re Paulsen* , 30 F.3d at 1479. *(C) The Dow Publications*

No dispute exists between the parties on the point that the Dow publications that defendant contends anticipate the '741 Reissue Patent were all before the patent examiner during the prosecution of the patent- in-suit. I therefore give the proper deference to the patent officer's finding of no anticipation with regard to these prior art references. *See Molins PLC,* 48 F.3d at 1186; *Kaufman,* 807 F.2d at 974.

The Dow publications advertise the use of DOWEX MONOSPHERE resins for water treatment. (Capital letters appear in original publications and indicate commercial product.) Dow states in its brochures that one selling point of this product is that these DOWEX MONOSPHERE resins do not vary significantly in size. "With DOWEX MONOSPHERE resins, you get 90% of the beads within +10% of the mean bead size. And with size control so precise, we measure DOWEX MONOSPHERE resins in microns rather than mesh sizes." Def.'s Ex. 521 at 3. *See also* Def.'s Ex. 522 entitled "Unprecedented

Page 1086

Bead Size Uniformity Provides Near-Perfect Separation in Condensate Polishers"; Def.'s Ex. 524 at 5 "New Monosphere Tough Gel TG" (stating that "outstanding bead size uniformity" is a feature that "translates into an array of added performance improvements"); Def.'s Ex. 523 at 3 "With DOWEX MONOSPHERE Resins" (stating that "since DOWEX MONOSPHERE resins have better size uniformity, less eluent is required").

No dispute exists between the parties that these DOWEX MONOSPHERE resins are precisely the ion exchange resin beads that the '741 Reissue Patent suggests as "suitable . . . for use in the present invention." *See* '741 Reissue Patent, col. 3, line 40. All parties agree, and I so conclude, (that the Dow publications disclose "substantially uniform size" ion exchange resin beads exactly as I have construed them.

[8] The parties do dispute, however, whether the Dow publications disclose "substantially uniform size" ion exchange resin beads in an EDI apparatus as described by the '741 Reissue Patent. For the reasons that follow, I conclude that no reasonable jury could find by clear and convincing evidence that the Dow publications disclose "substantially uniform size" ion exchange resin beads in an EDI apparatus as described by the '741 Reissue Patent.

The Dow publications do not describe any particular invention with specificity. On the contrary, the Dow publications are advertisements the goal of which is to convince others that the Dow products will improve certain processes for purifying liquid. One of these processes is chemically regenerated ion exchange, a process that uses chemicals, not electricity, to regenerate the ion resins that are used to deionize the liquid in the purifying machine. Another one of these processes may be electrodeionization, as is described by the '741 Reissue Patent. The Dow publications do not specify which process will be improved by their product, although credible and uncontroverted testimony of defendant's witness Dr. Kunin showed that the Dow publications relate to chemical regenerated ion exchange and not to electrodeionization. *See* Hearing Transcript, Vol. II at pp. 65-70.

The Dow publications focus, in general, on convincing the audience that the DOWEX MONOSPHERE resins would greatly enhance the capabilities and efficiency of water purifying processes. Plaintiffs admit to purchasing DOWEX MONOSPHERE resins and experimenting of water purifying processes. Plaintiffs admit to purchasing DOWEX MONOSPHERE resins and experimenting with them in their development of EDI apparatuses. And, under cross-examination, so do defendants. *See* Hearing Transcript, Vol. I at 44. When asked "isn't it true that [defendant] Ionics worked with both Dowex Monopshere Resins and other Dow resins during this later 1980 period when your research [on EDI] began to accelerate," defendant-witness Dr. goldstein (CEO of Ionics) admitted that he "would suspect that's correct." *Id.*

What both sides demonstrated during the three-day evidentiary hearing with regard to the Dow publications, then, was that the Dow publications were successful at convincing their audience of the value of Dow's products. What was also demonstrated, and was never in dispute, was that the DOWEX MONOSPHERE resins were the ion exchange resin beads used as a model of "substantially uniform size" in the EDI apparatus claimed by the '741 Reissue Patent. The mere experimentation and/or presence of these ion exchange resin beads in an EDI apparatus does not make the '741 Reissue Patent invalid, however. The prior art must disclose element for element, claim by claim, the invention at issue. *See In re Paulsen* , 30 F.3d at 1479. And, then, the prior art must also be enabling. *Id.*

Defendant failed to meet its burden on all of these accounts: no testimony or other admissible evidence was proffered that would allow a reasonable jury to find by clear and convincing evidence that the Dow publications anticipate and enable the claimed EDI invention as disclosed in the '741 Reissue Patent. One fact that the evidence proved to be beyond genuine dispute was the fact that the Dow publications advertise the sale of ion exchange resin beads of "substantially uniform size" for use by companies like defendant Ionics and plaintiff U.S. Filter in the development of their liquid purification processes, among other applications. This showing cannot be a showing of enablement, however, as I agree with the PTO that no EDI apparatus was described at all in the prior art at issue. *See Genentech* , 108 F.3d at 1366 (stating that " [t]ossing out the mere germ of an idea does not constitute enabling disclosure"). *(d) The Grebenyuk Article and The Sotskova Article*

No evidence before me shows that the patent examiner had the Grebenyuk article before him during the prosecution of the '741 Reissue Patent. The record shows that the patent examiner did have the Sotskova article before him, however, an article which is explicitly a continued analysis of the results and functioning of the apparatus described by the Grebenyuk article. *See* Sotskova article,

Page 1087

Pl's Ex. 25 at 1597 (stating that "the apparatus [to be compared with the present one] has already been described in detail" and then citing to the Grebenyuk article in footnote 8).

The Sotskova article describes itself as a comparison of the results from the EDI apparatus described in the Grebenyuk article with an EDI apparatus experimented upon by Sotskova and others that differs from the EDI apparatus in the Grebenyuk article "by the fact that there are contacts between ion exchangers of different kinds, *i.e.* there are dipolar boundaries." *Id.* at 1597. thus, as the Grebenyuk article and the EDI apparatus described therein are embodied in the Sotskova prior art reference, *i.e.* , the Grebenyuk article "is cumulative to other prior art that was before the patent examiner," *Engel Indus., Inc. v. Lockformer Co.* 946 F.2d 1528, 1533 [20 USPQ2d 1300] (Fed.Cir. 1991), I conclude that the deference owed to the patent examiner with regard to his finding that the Sotskova article does not anticipate the claimed EDI apparatus taught by '741 Reissue Patent is properly extended to the Grebenyuk article. *Id.* (stating that cumulative or less pertinent prior art references are not material to a finding of inequitable conduct when the more pertinent prior art has been cited to the patent examiner). Furthermore, as I must look to the Grebenyuk article in order to properly compare the EDI apparatuses as described by the Sotskova article to the claimed EDI apparatus as taught by the '741 Reissue Patent in order to make a determination as to anticipation, I infer that the patent examiner had to act similarly in order to do his job properly.

No evidence was proffered by the defendant that the Grebenyuk article or the Sotskova article discloses element for element and claim by claim the EDI apparatus taught by the '741 Reissue Patent. The only evidence proffered by defendant regarding the Grebenyuk article was for the purpose of proving that the Grebenyuk article discloses an EDI apparatus that uses "substantially similar size" ion exchange resin beads.

A careful reading of the Sotskova article reveals references to a mixture of KU-2 and AV-17 ion exchange resins in an EDI apparatus (*see* Sotskova article at 1597) as well as "macroporous KU-2P-6, KU-2P-10, and KU-2P-16 cation-exchange resins . . . mixed with AV-17P macroporous anion-exchange resins." *see id.* at 1598. The article indicates the size of the resin beads only as to the latter mixture. It reads " [t]o ensure an identical sorption surface in all the mixtures, resin fractions with 0.8-1 mm grain diameters were selected." *Id.* The article does not indicate how that size was attained, whether resin beads were sieved, hydraulically separated or purchased as ostensibly all of substantially the same size. Neither defendant nor plaintiffs proffered any evidence to the court that would illunminate these references in the Sotskova article.

Much of the presentations by the parties during the hearing concerned the size of the ion exchange resins disclosed in the experiment described in the Grebenyuk article to which the Sotskova article refers. Like the Sotskova article, the Grebenyuk article also refers to a mixture of KU-2 and AV-17 resins. *See* Grebenyuk article at 987. But unlike the Sotskova article, the Grebenyuk article states that " [b]y screening through a sieve, a grain fraction with a 0.49-0.51 mm diameter was selected. To separate spherical grains from fragments and irregular granules, the chosen resin fraction was poured on to an inclined plane while the fragments remained." *Id.*

The oral testimony and written declarations in evidence regarding the accuracy and reliability of sieving as a process to control for bead size is as applicable to the comparison of the Grebenyuk

article to the patent-in-suit as it was to the comparison of the Gittens and Watts article to the patent-in-suit. *See supra* Part V. A. 4(b). Defendant's witnesses concede that sieving is an imperfect process, made more imperfect by the lack of a record of actual measurements in the Grebenyuk article (as is the case in the Gittens and Watts article). *See* Hearing Transcript, Vol. II at 79-80. Furthermore, the uncontroverted testimony before the court was that (in order to be as accurate as possible, and how accurate is still unclear from the evidence before me) resin beads must be sieved through two meshes in order to calculate the proper range of diameters in which all the resulting resin beads should fall. *See id. See also* Hearing Transcript, Vol. I at 140. But as Dr. Kunin conceded on cross-examination, the Grebenyuk article used resin beads that were screened through only one sieve, not two. *See* Hearing transcript, Vol. II at 79. *See also* Grebenyuk article at 987 ("by screening through *a* sieve . . .") (emphasis added). Upon realizing his mistaken assumption with regard to the Grebenyuk article, Dr. Kunin admitted as correct that "It's not possible to get a range" using a single sieve and that "the article doesn't say how many times the samples were sieved" and that " [the Grebenyuk article] gives no details on [the authors'] sieving procedure." *Id.*

Given the defendant's witness admitted that the sieving procedure used by Grebenyuk was flawed -- a sieving procedure the

Page 1088

reliability of which was already brought into doubt by he previous testimony regarding the Gittens and Watts article of defense witnesses Drs. Gittens and Kunin -- little (if any) credible evidence remains before the court that could be considered as support for a determination that defendant could show that the Grebenyuk article discloses to one of ordinary skill in the art the use of "substantially uniform size" ion exchange resin beads in an EDI apparatus just like the one taught by the '741 Reissue Patent. On the contrary, the evidence is overwhelmingly in favor of the plaintiffs; even when the admissible evidence is considered in a light favorable to the defendant, I conclude that no reasonable jury could find by clear and convincing evidence that the Grebenyuk article and the Sotskova article disclose to a person or ordinary skill in the art the use of "substantially uniform size" ion exchange resin beads in the EDI apparatus as claimed by the '741 Reissue Patent.

Finally, as noted earlier in part V. A. 4(b) above, defendant proffered no testimony or other evidence that compared all the other elements of the allegedly anticipated claims of the '741 Reissue Patent to the apparatus described in the Grebenyuk article and the Sotskova article. In fact, Dr. Kunin admitted under cross-examination that the Grebenyuk article (and by association the Sotskova article) does not disclose (and therefore cannot enable) many of the undisputed elements of the allegedly anticipated claims of the '741 Reissue Patent. Among these are elements such as separate ion depleting and ion concentrating compartments or subcompartments made of permeable membranes and a pair of ribs. *See* Hearing Transcript, Vol. II at 75-76. Thus, even if a higher court wee to disagree with my determination today that no reasonable jury could find by clear and convincing evidence that "substantially uniform size" ion exchange resin beads as I have construed them are disclosed by the Grebenyuk and Sostkova articles, defendant has still not met its burden, in relation to a motion for summary judgment, to prove that no genuine dispute of material fact exists as to the anticipation of all the elements of all the disputed claims of the '741 Reissue Patent by the prior art.

B. Recapture

Defendant's second argument for invalidating the '741 Reissue Patent is that plaintiffs impermissibly recaptured subject matter in the '741 Reissue Patent that was surrendered during the prosecution of the original patent. *1. Facts as to Recapture*

The '741 Reissue Patent reissued from the '809 Patent. On the face of the '741 Reissue Patent, the PTO names "Related U.S. Patent Documents" as follows:

Reissue of:

Patent No.: 5,154,809 Issued: Oct. 13, 1992 Appl. No.: 417,950 Filed: Oct. 6, 1989

U.S. Applications:

Continuation of Ser. No. 613,075, Mar. 8, 1996, abandoned, which is continuation of Ser. No. 332,187, Oct. 12, 1994, abandoned, which is a continuation of Ser. No. 908,913, Sep. 18, 1986, Pat. No. 4,925,541, which is a division of Ser. No. 762,804, Aug. 2, 1985, Pat. No. 4,632,745, which is a continuation of Ser. No. 628,930, Jul. 9, 1984, abandoned, said Ser. No. 417,950, Oct. 6, 1989, Pat. No. 5,154,809, is a continuation-in-part of Ser. No.

> 275,314, Nov. 23, 1988, Pat. No. 4,931,160, which is a continuation of Ser. No. 48,161, May 11, 1987, abandoned.

'741 Reissue Patent at 1.

The genealogy of the '809 Patent as quoted above and as stated on the first page of the '741 Reissue Patent indicates that the '809 Patent is a derivation of two lines of patent applications and patents. One line begins with abandoned application number 628,930 from which emerges the divisional application number 762,804, which issues as Patent No. 4,632,745 (" '745 Patent"). Also from the 762,804 application emerges the divisional application number 908,913 which issues as Patent No. 4,925,541 (" '541 Patent"). And then also from the 908,913 application emerges the continuation applications number 322,187 and 613,075, both of which were abandoned. The other line of patent applications and patents from which the '809 Patent emerges begins with the abandoned application number 48,161. From that application emerges the continuation application number 275,314 which issues as Patent No. 4,931,160 (" '160 Patent"). Also from the application number 275,314 emerges the '809 Patent as a continuation-in-part.

Many claim limitations of the '809 Patent were amended and became part of the '741 Reissue Patent. The only limitation defendant disputes as impermissibly recapturing limitations previously surrendered, however, is the word "secured" in the '741 Reissue Patent that replaces "bonded" in the '809 Patent. This "secured" language is in claims 4 and 11 of the '741 Reissue Patent (and

Page 1089

thus also in claims 5-8 and 12-18 that are dependent on claims 4 and 11) and appears as follows:

> "4. . . . [said anion permeable membrane and the said cation permeable membrane being bonded] *the anion exchange membrane and the cation exchange membrane each being secured to* a spacer to [effect sealing against water] *create a seal against liquid* leakage between [said] *the* ion [depletion] *depleting* compartment. . . . 11. . . .each of [said] *the* ion permeable membranes being [bonded] *secured to* a spacer and [said] *the* ribs within [a] *the* spacer such that the anion permeable membrane and *the* cation permeable membrane are positioned alternatively along [said] *the* length of the dual compartment."

'741 Patent, col. 13, lines 30-34, and col. 14, lines 50 (all italics and brackets in the text of the '741 Reissue Patent) (brackets indicate words in the '809 Patent that were omitted from the '741 Reissue Patent and italics indicate the words that were added to the '741 Reissue Patent). *2. Applicable Law*

35 U.S.C. Section 251 (1954) is the section of the Patent Act that allows for reissuance of patents under certain circumstances. In pertinent part, the section reads as follows:

> Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patent claiming more or less than he had a right to claim in the patent, the Commissioner shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent for the invention disclosed in the original patent, and in accordance with a new and amended application, for the unexpired part of the term of the original patent. No new matter shall be introduced into the application for reissue. . . .

No reissued patent shall be granted enlarging the scope of the claims of the original patent unless applied for within two years from the grant of the original patent.

Id.

The so-called "recapture rule," which flows from Section 251 of 35 U.S.C., prevents a patentee from regaining through reissue the subject matter surrendered during the prosecution of the original patent in an effort to obtain allowance of that original patent. *See Mentor Corp.* v. *Coloplast,* 998 F.2d 992, 995 [27 USPQ2d 1521] (Fed.Cir. 1993). Under this rule, claims that are "broader than the original patent claims in a manner directly pertinent to the subject matter surrendered during prosecution" are impermissible and therefore invalid. *Id.* at 996.

[9] The first step for a court in applying the recapture rule is to determine whether and in what aspect the reissue claims are broader than the patent claims. *In re Clement,* 131 F.3d 1464, 1468 [45 USPQ2d 1161] (Fed.Cir. 1997). Of course, a reissue claim that is narrower in scope than the original application escapes the recapture rule entirely. *See Ball Corp.* v. *United States,* 729 F.2d 1429, 1436

[221 USPQ2d 289] (Fed.Cir. 1984).

The second step is to determine whether the broader aspects of the reissued claims relate to surrendered subject matter and, if they do, to determine whether the broader claims are an attempt to recapture, impermissibly, limitations that were surrendered in order to overcome prior art rejection. *In re Clement,* 131 F.3d at 1468. This determination requires an examination of the prosecution history of the original patent. *Id.* at 1469. *3. Parties' Positions*

The first argument between the parties concerns the meaning of "original" in the reissue statute, 35 U.S.C. Section 251. Plaintiffs say that "original" means the patent to which the patent examiner looks to correct the alleged "error" that Section 251 allows. In other words, the "original" patent is the patent from which the new *corrected* patent reissues. In the present case, the '741 Reissue Patent is a reissuance of the '809 Patent, *i.e.,* the '741 Reissue Patent corrects errors made in the '809 Patent. Therefore, plaintiffs argue, the court must look to the prosecution history of and the application for the '809 Patent to examine whether during that prosecution any language relating to "bonded" was surrendered in order to overcome prior art rejections.

Defendant argues that "original" means all of the patents in the '809 family, that is, all of the applications (abandoned and continued) and all of the issued patents that preceded the '809 Patent and from which the application of the '809 Patent is a divisional, continuation and a continuation-in-part application. *See* '809 Patent, Def.'s Ex. 502 at 1 "Related U.S. Application Data." [1] Under

Page 1090

defendant's theory, a reviewing court, such as this court in this case, would have to look at all the applications related in any way to the '809 Patent -- those that eventually issued a patents and those that were abandoned -- and to their prosecutions to determine if a claim limitation was surrendered that relates to the present disputed claim element "secured" of the reissued patent.

---

[1] The genealogy of the '809 Patent as related in the text of the '809 Patent differs from the genealogy related in the '741 Reissue patent. The "Related U.S. Application Data" in the '809 Patent reads "Continuation-in-part of Ser. No. 908,913, Sep. 18, 1986, Pat. No. 4,925,541, which is a division of Ser. No. 762,804, Aug. 2, 1985, Pat. No. 4,632,745, which is a continuation of Ser. No. 628,930, Jul. 9, 1984, abandoned." The relevant difference between this genealogy and the one related in the '741 Reissue Patent is that in the text of the '809 Patent, the '809 Patent is a continuation-in-part of the application number 908,913 whereas in the text of the '741 Reissue Patent, the '809 Patent is a continuation of application number 908,913 not a continuation-in-part. In a continuation application, the applicant has reformulated her claims after a rejection by the PTO, whereas in a continuation-in-part application, the applicant has supplemented her original application -- the specification and the claims -- with new subject matter to cover improvements made since the first application was filed. The difference does not matter for the analysis and my conclusion that follow, but I not the difference in order to remark upon the ambiguity in the genealogy of the patents, and ambiguity that makes a reasoned and thorough culling of the "family of patents and their applications" for indications as to why some applications were rejected and why others were not, a position defendant's urge upon this court, a very difficult position to sustain.

To support its argument, defendant cites to a recent case, *Elkay Manufacturing Company* v. *Ebco Manufacturing Company and Ebtech Corp.,* 1999 U.S.App. LEXIS 22279 [52 USPQ2d 1109] (Fed.Cir. Sept. 15, 1999) in which the opinion states that " [w]hen multiple patents derive from the same initial application, the prosecution history regarding that claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same limitation." *Id* . at *17-*18. What defendant does not say is that *Elkay* is a case that centers around a district court's claim construction that was dispositive of the issue of patent infringement before it. *Elkay* is not a recapture case and does not purport to be referring to the "original" patent as that term is used in Section 251 of the Patent Act.

In citing *Elkay* as support for its recapture analysis, defendant confuses the court's role in construing claims for the purposes of an infringement analysis with the court's role in looking to the prosecution history of a first patent that reissues as a second patent due to some error in the first patent. In claim construction, the court must give meaning to patent claims and compare that meaning to allegedly infringing devices. The court does so, sometimes, by looking to the prosecution history if, for example, some assertion is made that the words have a meaning other than their plain and customary meaning.

See Renishaw PLC , 158 F.2d at 1249. By contrast, in a recapture analysis, the court compares the claim limitation of a reissued patent that was changed as a result of an error in the first patent, and, based on the prosecution history of the first patent that concerns that limitation, determines whether or not the reissued claim limitation incorporates language that was purposely omitted from the first patent as a result of the PTO's prior art evaluation. Although, in both cases, the court looks to the prosecution histories of patents, the court does so for different reasons.

[10] To do as defendant asks would require scouring through multiple prior applications (some abandoned and some pursued) and prosecution histories, some that only remotely relate to the subject matter of the patent at issue and some that may more directly relate to it, looking for explanations of surrendered subject matter and determining whether those explanations should render invalid the reissued patent. This is not an exercise for the court that is likely to lead to sensible results. It is also not an exercise in which Section 251 of the Patent Act requires that a reviewing court engage. Furthermore, no good reason exists to interpret the word "original" in the Section 251 of the Patent Act to mean anything other than its common-sense meaning; the "original" patent is the patent that is *corrected* by the reissue patent. Defendant is misguided by defendant's misinterpretation of the language in Elkay and by applying that language to a recapture analysis. Therefore, I conclude that I must look only to the prosecution history of the '809 Patent, the "original" patent with regard to the '741 Reissue Patent, in order to determine whether language relating to "secured" was surrendered during prosecution of the '809 Patent to overcome some prior art rejection, which would then render the corresponding claims of the '741 Reissue Patent invalid.

Because I so conclude, the testimony and evidence relating to the patents and patent applications other than the '809 Patent and

Page 1091

the '741 Reissue Patent that were offered for the purpose of showing impermissible recapture of subject matter are irrelevant. This includes Def's Exhibits Nos. 509 (Prosecution History of Patent Application No. 628,930), 510 (Prosecution History of Patent Application No. 762,804), 511 (Prosecution History of Patent Application No. 908,913), 512 (Prosecution History of Patent Application No. 48,161), 513 (Prosecution History of Patent Application No. 275,314), 515 (Prosecution History of Patent Application No. 322,187), 515 (Prosecution History of Patent Application No. 617,075), 516 Patent No. '541), 517 (Patent No. '160), 518 (Defendant's Rendition of the "Family Tree" of '741 Reissue Patent), and the following paragraphs of Docket No. 196, Lappin Declaration: Para.4 (except for the statements regarding the application number 417,950, the '741 Reissue Patent and the '809 Patent), Paragraphs7-26, Para.28, Para.34, Para.35, Para.42 (only the last paragraph beginning "The PTO examiner who explained . . ."), Para.47, Para.48. Other objections regarding paragraphs of the Lappin Declaration to which I have thus far not responded are *overruled. 4. Application of Law of Recapture to Facts (a) Is "Secured" Broader than "Bonded"*

The only change from the '809 Patent to the '741 Reissue patent that defendant disputes is the word "bonded" in the '809 Patent to the word "secured" in the '741 Reissue Patent. Two propositions, besides common sense and ordinary meaning, led me to the conclusion that "secured" is a broader term than "bonded." The first proposition is that the specification of the '741 Reissue Patent itself defines the word "bonded" as a subset of the word "secured." *See* 741 Reissue Patent, col. 4, lines 54-55 ("securing, such as by bonding"). The second proposition is that in the prosecution of the reissue application 778,714 which issued as the '741 Reissue Patent, the patent applicants declared to the patent officer in the required declarations that one of the errors in the original patent was that it did not claim as much as the applicants had a right to claim, in particular, the membranes did not have to be "bonded" together but could be secured by other means. *See* Def.'s Ex. 505 at 117072-83. Based on the '741 Reissue Patent specification and the declarations of the inventors of the apparatus described by the '809 Patent, as well as on common sense and ordinary meaning, I conclude that "secured" is broader in meaning than "bonded" as those words appear in the '741 and '809 Patents respectively. *(ii) Does the term "Secured" Relate to Subject Matter Surrendered in the Prosecution of the '809 Patent?*

[11] The prosecution history of the '809 Patent demonstrates that the term "bonded" appears in the application for the '809 Patent (application number 417,950 (the " '950 application")) exactly as it appears in the issued patent. *Compare* Def.'s Ex. 504 at 117194-200 *with* Def.'s Ex. 502, col. 12, line 58; col. 12, line 42; and col. 14, line 59. This indicates that any changes made in the application to overcome prior art rejections did not have to do with the word "bonded". *See* Def.'s Ex. 504 at

117194-200. Furthermore, a thorough review of the prosecution history of the '809 Patent reveals that no substantive changes were made to the claims as written in the '950 application in order to be issued as the '809 Patent. The changes that were made were procedural, *e.g.,* filing a terminal disclaimer to overcome the PTO's rejection based on the judicially created doctrine of obviousness-type double patenting, *see id.* at 117242-45, and amending the "Reference to Related Applications" to indicate prior issued patents to which the '950 application relates. *See id.* at 117231-34. This review of the prosecution history demonstrates that nothing was surrendered during the prosecution of the '809 patent that relates to "bonded."

Nothing having been surrendered, the change from "bonded" in the '809 Patent to "secured" in the '741 Reissue Patent cannot be an impermissible recapture. I therefore conclude that no jury could reasonably find by clear and convincing evidence that the '741 Reissue Patent is invalid for violating the recapture rule.

C. Assent of Assignee

Defendant's last argument to invalidate the '741 Reissue Patent is that plaintiffs failed to obtain the assent of the proper assignee of the '809 Patent when the reissue application was filed. This procedural flaw, defendant argues, is the basis for patent invalidity. *1. Facts as to Assent of Assignee*

No dispute exists as to the facts regarding plaintiffs' failure to list the proper assignee of the '809 Patent on the reissue application. The pertinent undisputed facts are as follows:

Page 1092

On December 14, 1993, Millipore Corporation ("Millipore Corporation"), a Massachusetts corporation, who at the time was the sole and exclusive owner of '809 Patent, assigned its entire right, title and interest in the '809 Patent to its wholly-owned subsidiary Millipore Investment Holdings Limited ("Millipore Investment"), a Delaware corporation. *See* Def.'s Ex. 508 at 1, 5.

On October 12, 1994, the inventors named in the original '809 Patent filed an application for reissue of the patent and as part of the reissue application, filed with the PTO a document entitled "Assent of Assignee." The document identified Millipore Corporation as the "assignee of the entire right, title and interest in the '809 Patent." *See* Def.'s Ex. 504 at 11727; Pl.'s Ex. 5.

The parties do not contest the fact that the "Assent of Assignee" contained an inadvertent error. It identified Millipore Corporation instead of Millipore Investment Holdings as the assignee of the "entire right, title and interest" in the '809 Patent.

On March 10, 1998, the PTO reissued the '809 Patent as the '741 Reissue Patent apparently without notice of the error in the "Assent of Assignee" as the '741 Reissue Patent names on its face the "Assignee: Millipore Corporation, Bedford, MA." *See* Def.'s Ex. 501.

On or about March 9, 1999, Millipore Investment filed with the PTO a written Nunc Pro Tunc Assent to the reissue of the '809 Patent as the '741 Reissue Patent. The PTO accepted Millipore Investment's Nunc Pro Tunc Assent for recording. *See* Pl.'s Ex. 7. *2. Applicable Law*

"Inequitable conduct resides in failure to disclose material information, or submission of false material information, with an intent to deceive, and those two elements, materiality and intent, must be proven by clear and convincing evidence." *Kingsdown Medical consultants v. Hollister Inc.* , 863 F.2d 867, 872 [9 USPQ2d 1384] (Fed.Cir. 1988). More recently the Federal Circuit has reiterated:

> Technical violations of PTO procedures, absent fraud or intentional deception, are not inequitable conduct as would invalidate the patent. The courts have consistently rejected the notion of per se forfeiture [of patent rights] based on non-fraudulent failure to comply with a rule of practice before the PTO.

Seiko Epson Corp. v. Nu-Kote Int'l , 1999 WL 695199 (Fed.Cir. 1999) at *6-7 [52 USPQ2d 1011] *citing Hebert v. Lisle Corp.* , 99 F.3d 1109, 1116 [40 USPQ2d 1611] (Fed.Cir. 1996) ("A holding of unenforceability based on the filing of a false oath requires that the oath was false, and made with knowledge of the falsity . . . . Knowledge of falsity is predicate to intent to deceive.") and *Molins PLC v. Textron, Inc.* , 48 F.3d 1172, 1184 [33 USPQ2d 1823] (Fed.Cir. 1995) ("intent to deceive should be determined in light of the realities of patent practice, and not as a matter of

strict liability whatever the nature of the action before the PTO").

According to Federal Circuit precedent, proof of inequitable conduct before the PTO requires the district court to engage in a two-step analysis. First, the district court decides whether the proffer of admissible evidence before it supports a finding by clear and convincing evidence "of both materiality with regard to the omitted information, and of deceptive intent in the withholding of information." *Akron Polymer Container Corp. v. Exxel Container, Inc.* , 148 F.3d 1380, 1383 [47 USPQ2d 1533] (Fed.Cir. 1998) (citations omitted). Second, the court weighs at once the degrees of materiality and intent and decides, "in the sound exercise of its equitable discretion . . . whether inequitable conduct has occurred." *See id. 3. Relevance Rulings*

Defendant objected to the relevance of plaintiffs' proffers of the following written declarations that were proffered for the purpose of defending against defendant's allegations of fraud on the PTO: Docket No. 184, Affidavit of Andrew T. Karnakis, employed by Millipore Corporation and Millipore Investment as Assistant General Counsel and Director of Patents and Licensing between the years 1983-1996; Docket No. 185, Affidavit of Peter C. Lando, attorney of record for the prosecution of the '741 Reissue Patent on behalf of U.S. Filter Corporation; Docket No. 186, Affidavit of Peter W. Walcott, Executive Vice President, Secretary, and a Director of Millipore Investment, and, for the past eighteen years, the Assistant General Counsel of Millipore Corporation. I now determine that the relevance of these affidavits is not outweighed by other factors to be considered by this court under Federal Rule of Evidence 403 and that these affidavits have sufficient probative weight for the purpose for which they were proffered. *4. Applying Facts to Law*

It is undisputed that plaintiffs failed to comply with section 1.172 of title 37 of the Code of Federal Regulations that requires that upon application of a reissue patent, a

Page 1093

"reissue oath must be signed and sworn to by the . . . inventors . . . and must be accompanied by the written consent of all assignees. . ." 37 C.F.R. Section 1.172. It is also undisputed that plaintiffs did not intend to deceive or defraud the PTO. The core of the parties' dispute is whether the error in misnaming the assignee in the "Assent of Assignee" as Millipore Corporation instead of Millipore Investment is a material error.

Plaintiffs argue that the inadvertent mis-naming of the assignee was harmless procedural error that cannot be a basis for invalidating an otherwise valid patent. They proffer evidence, which defendant does not contest, that shows that the reissue application was filed with the knowledge, authorization and permission of Millipore Investment and on its behalf as the true assignee despite the fact that Millipore Corporation was listed as the alleged assignee. *See* Docket No. 186, Walcott Affidavit, Paragraphs12-13. *See also* Docket No. 184, Karnakis Affidavit, Para.7. Plaintiffs also assert through various uncontested affidavits that the reissue application would have been prosecuted in an identical manner had Millipore Investment been identified as the assignee instead of Millipore Corporation. *See id.* at Para.14; Docket No. 185, Lando Affidavit, Para.17. These proffers of uncontested evidence, plaintiffs assert, together prove that no inequitable conduct occurred with regard to the prosecution of the '741 Reissue Patent. Thus, plaintiffs argue, defendant's third attack on the validity of the '741 Reissue Patent should fail as a matter of law.

[12] Defendant argues that an error of this sort -- falsely naming the assignee in a reissue patent application -- is reason to invalidate the patent because the PTO's requirement of the filing of an assent of assignee with a reissue patent is a "substantive rule [] [t]he purpose of [which] . . . is to prevent somebody who doesn't own the patent from seeking to vary the scope of the patent rights without permission of the owner of the patent." Hearing Transcript, Vol. III at 21. This argument I understand to be directed toward the materiality prong of the inequitable conduct test. Without satisfying the "intent to deceive" prong, however, defendant's argument fails as a matter of law.

Thus, I now determine on the evidence before me, as a matter of law, that plaintiffs' error in naming Millipore Corporation instead of Millipore Investment as the assignee of the '809 Patent for the purposes of the reissue application cannot rise to the level of inequitable conduct that would require the '741 Reissue Patent to be held invalid.

VI. Remaining Relevancy Objections

Remaining for consideration are objections to the relevance of other proffers of evidence identified in this paragraph. Those objections relate to Docket No. 194, Direct Testimony of Arthur L. Goldstein,

Paragraphs 2-6 and 11-12, and Plaintiffs' Exhibit No. 17. I now determine these objections to be moot. The court's findings of fact and the evaluative determinations applying law to the factual circumstances of this case have been recited and explained throughout this opinion. In no instance has the court's decision depended in any degree on whether or not it should consider any of these outstanding challenged proffers of evidence. Even if the challenged evidence could be taken as satisfying the threshold of relevance, in no instance was it of sufficient probative weight to affect the court's finding of fact or evaluative determination.

ORDER

For the foregoing reasons, it is ORDERED: (1) Defendant's Motion for Summary Judgment of Invalidity of the Patent In Suit (Docket No. 92, filed December 21, 1998) is DENIED;

(2) Plaintiff's Motion for Partial Summary Adjudication (submitted orally at the evidentiary hearing, *see* Hearing Transcript, Vol. III at 40) with regard to defendant's claim of patent invalidity for reasons of anticipation, impermissible recapture of surrendered subject matter, and an erroneously-designated assent of assignee of a patent for which a reissue application was pending is ALLOWED. *These defense contentions of patent invalidity are rejected as a matter of law.*

- End of Case -

ISSN 1526-8535

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > Genentech Inc. v. Novo N
42 USPQ2d 1001 (Fed. Cir. 1997)

42 USPQ2d 1001
Genentech Inc. v. Novo Nordisk A/S
U.S. Court of Appeals Federal Circuit

No. 96-1440

Decided March 13, 1997

108 F3d 1361

Headnotes

PATENTS

[1] Patentability/Validity -- Specification -- Enablement (► 115.1105)

Specification of patent in suit would not have enabled person of ordinary skill in art at time of filing to use cleavable fusion expression to make human growth hormone without undue experimentation, since specification merely describes three or four applications for which cleavable fusion expression is generally well-suited, and names enzyme that might be used as cleavage agent as well as sites at which it cleaves, and thus does not describe specific material to be cleaved or any reaction conditions under which cleavable fusion expression would work, and since evidence does not support patentee's contention that disclosure of DNA encoding hGH, combined with prior art cleavable fusion expression techniques applied to non-human proteins, would enable practice of claimed method.

[2] Patentability/Validity -- Specification -- Enablement (► 115.1105)

Rule that specification need not disclose what is well known in art means only that omission of minor details does not cause specification to fail to meet enablement requirement, and is not substitute for basic enabling disclosure; if there is no disclosure of any starting material or of any conditions under which claimed process can be carried out, undue experimentation is required, and there is failure to meet enablement requirement that cannot be rectified by asserting that all disclosure related to process is within skill of art.

[3] Patentability/Validity -- Specification -- Enablement (► 115.1105)

Specification that states problem of obtaining human growth hormone from precursor containing added protein material does not enable claim for method of producing hGH using cleavable fusion expression, since specification discloses method in which problem is solved by obtaining hGH unaccompanied by leader sequence or other extraneous proteins, but does not provide specific enabling disclosure for obtaining hGH by cleaving hGH-containing protein as recited in claim.

[4] Patentability/Validity -- Specification -- Enablement (► 115.1105)

Fact that no one had been able to produce any human protein via cleavable fusion expression as of application date of patent in suit undermines patentee's contention that specification's disclosure of DNA sequence encoding human growth hormone and single example enzyme and its cleavage site, without more, would have enabled one skilled in art to have used claimed cleavable fusion expression method to make hGH without undue experimentation; moreover, if disclosure of useful conjugate protein and method for its cleavage were clearly within skill of art, as patentee asserts, it would have been expressly disclosed in specification, and in customary detail.

Page 1002

Particular Patents

Particular patents -- Chemical -- Human growth hormone

5,424,199, Goeddel and Heyneker, human growth hormone, invalid for lack of enablement.

Case History and Disposition

Appeal from the U.S. District Court for the Southern District of New York, Motley, J.

Action by Genentech Inc. against Novo Nordisk A/S, Novo Nordisk of North America Inc., and Novo Nordisk Pharmaceuticals Inc. for patent infringement. From grant of plaintiff's motion for preliminary injunction, defendants appeal. Injunction vacated; patent held invalid as matter of law for failure of specification to enable practice of claimed method.

Prior decision: 37 USPQ2d 1773 .

Attorneys

Leora Ben-Ami, John E. Kidd, Nicholas L. Coch, Joseph Ferraro, Philip E. Roux, and Gerard P. Norton, of Rogers & Wells, New York, N.Y.; Ryan Trainer, of Rogers & Wells, Washington, D.C., for plaintiff-appellee.

Albert L. Jacobs Jr., Jesse D. Reingold, Gerard F. Diebner, Daniel A. Ladow, Brad S. Needleman, and Andrew T. Solomon, of Graham & James, New York; John C. Vassil, Kurt E. Richter, and Kenneth H. Sonnenfeld, of Morgan & Finnegan, New York, for defendants-appellants.

Judge

Before Archer chief judge, and Lourie and Bryson, circuit judges.

Opinion Text

Opinion By:

Lourie, J.

Novo Nordisk A/S, Novo Nordisk of North America, Inc., and Novo Nordisk Pharmaceuticals, Inc. (collectively "Novo") appeal from the order of the United States District Court for the Southern District of New York, issuing a preliminary injunction in favor of Genentech, Inc., enjoining Novo from importing, marketing, using, selling, offering for sale or distributing its Norditropin(Registered)-brand recombinant human growth hormone (hGH) product. *Genentech, Inc. v. Novo Nordisk A/S* , 935 F.Supp. 260 (S.D.N.Y. 1996). Because the district court's conclusion that Genentech had demonstrated a likelihood of success on the merits was based on an error of law and because its remaining findings were premised on this error, we vacate the injunction.

BACKGROUND

This consolidated patent infringement action was first brought in the United States District Court for the Southern District of New York on November 30, 1994. On May 12, 1995, Genentech moved for a preliminary injunction under U.S. Patent 4,601,980 to prevent Novo from importing, marketing, using, selling, offering for sale or distributing in the United States its Norditropin(Registered)-brand recombinant hGH product. The district court granted Genentech's motion and issued an injunction. *Novo Nordisk of North Am., Inc. v. Genentech, Inc.* , No. 94 Civ. 8634 (CBM), 1995 U.S. Dist. LEXIS 12588, 1995 WL 512171 (S.D.N.Y. Aug. 28, 1995).

On appeal this court vacated the injunction. *Novo Nordisk of North Am., Inc. v. Genentech, Inc.* , 77 F.3d 1364, 37 USPQ2d 1773 (Fed.Cir. 1996). We held that the district court clearly erred in finding that Genentech established a likelihood of proving infringement of the '980 patent because that finding was based on an improper construction of claim 2 of the patent. Based upon the specification and prosecution history, we concluded that because the claim used the phrase "human growth hormone unaccompanied by . . . other extraneous protein," it was limited to processes for directly expressing either hGH or met-hGH. *Id.* at 1371, 37 USPQ2d at 1779. Because the parties agreed that Novo did not use direct expression to produce these proteins, we concluded that Novo did not infringe the patent. *Id.*

Upon returning to the district court, Genentech asserted its newly issued U.S. Patent 5,424,199. The '199 patent has the same specification as the '980 patent and contains a single claim directed to:

> [a] method of producing a protein consisting essentially of amino acids 1-191 of human growth hormone comprising:
>
> (a) expressing in a transformant bacterium, DNA coding for a human growth hormone conjugate protein, which conjugate protein consists essentially of amino acids 1-191 of human growth hormone as set forth in combined Figs. 1 and 3 unaccompanied by the leader sequence of human growth hormone or other extraneous protein bound thereto and an additional amino acid sequence which is specifically cleavable by enzymatic action, and
>
> (b) cleaving extracellularly said conjugate protein by enzymatic action to produce said protein consisting essentially of amino acids 1-191 of human growth hormone.

Page 1003

This claim differs from the claim adjudicated in the prior case in reciting that the encoded protein has an additional amino acid sequence and includes the step of cleaving this conjugate protein. This process of expressing a DNA encoding a conjugate protein and using an enzyme to cleave off an undesired portion of that protein is generally known as cleavable fusion expression. The parties agree that Novo uses cleavable fusion expression to produce hGH. *Id.*

On June 27, 1996, after conducting a twelve-day evidentiary hearing, the district court again issued a preliminary injunction, this time based upon the '199 patent, enjoining Novo from importing, marketing, using, selling, offering for sale, or distributing in the United States its Norditropin (Registered)-brand recombinant hGH product. *Genentech v. Novo Nordisk A/S* , 935 F.Supp. 260 (S.D.N.Y. 1996). The district court based its decision upon, *inter alia* , a finding that Genentech would likely overcome Novo's defense that the '199 patent was invalid for lack of an enabling disclosure under 35 U.S.C. Section 112, Para. 1 (1994).

Novo appeals to this court, challenging the grant of the preliminary injunction. [1] We have jurisdiction pursuant to 28 U.S.C. Section 1292 (c) (1994).

---

[1] On July 3, Novo moved for an emergency stay of the injunction pending disposition of this appeal. On August 1, we denied Novo's motion and reinstated the injunction. However, after having heard oral argument in this case, we reconsidered the motion and reinstated the stay of the injunction.

DISCUSSION

The grant or denial of a preliminary injunction pursuant to 35 U.S.C. Section 283 is within the discretion of a district court. *We Care, Inc. v. Ultra-Mark Int'l Corp.* , 930 F.2d 1567, 1570, 18 USPQ2d 1562, 1564 (Fed.Cir. 1991). Accordingly, a trial court's decision granting a preliminary injunction will be overturned on appeal only upon a showing that the court abused its discretion. *Joy Techs., Inc. v. Flakt, Inc.* , 6 F.3d 770, 772, 28 USPQ2d 1378, 1380 (Fed.Cir. 1993). Such an abuse of discretion may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings. *Id.*

As the moving party, Genentech had to establish its right to a preliminary injunction in light of four factors: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if the injunction were not granted; (3) the balance of the hardships; and (4) the impact of the injunction on the public interest. *Nutrition 21 v. United States* , 930 F.2d 867, 869, 18 USPQ2d 1347, 1348-49 (Fed.Cir. 1991); *Hybritech Inc. v. Abbott Lab.* , 849 F.2d 1446, 1451, 7 USPQ2d 1191, 1195 (Fed.Cir. 1988).

A. *Likelihood of Success on the Merits*

In order to demonstrate that it has a likelihood of success, Genentech must show that, in light of the presumptions and burdens that will inhere at trial on the merits, (1) it will likely prove that Novo infringes the '199 patent and (2) its infringement claim will likely withstand Novo's challenges to the validity and enforceability of the '199 patent. *See New England Braiding Co. v. A.W. Chesterton Co.* , 970 F.2d 878, 882-83, 23 USPQ2d 1622, 1625-26 (Fed.Cir. 1992). [2] In other words, if Novo raises a "substantial question" concerning validity, enforceability, or infringement (*i.e.* , asserts a defense that Genentech cannot show "lacks substantial merit") the preliminary injunction should not issue. *Id.* More

specifically, with regard to Novo's validity defenses, the question on appeal is whether there is substantial merit to Novo's assertion that the '199 patent claim fails to meet the requirements of 35 U.S.C. Section 112, Para. 1 (1994).

[2] A patent is presumed valid, 35 U.S.C. Section 282 (1994), and a party challenging validity must prove invalidity by clear and convincing evidence. "However, the presumption does not relieve a patentee who moves for preliminary injunction from carrying the normal burden of demonstrating that it will likely succeed on all disputed liability issues at trial, even when the issue concerns the patent's validity." *New England Braiding* , 970 F.2d at 882, 23 USPQ2d at 1625 (citing *Nutrition 21* , 930 F.2d at 869, 18 USPQ2d at 1349).

Novo argues that the district court's findings regarding validity under Section 112, Para. 1, are clearly erroneous because it presented clear and convincing evidence that the patent specification would not have enabled a person of ordinary skill in the art to practice the claimed invention without undue experimentation. Novo also argues that the specification fails to contain a written description of the claimed invention. Regarding enablement, Novo argues that the patent is invalid because it does not contain sufficient detail concerning the practice of the claimed method. Novo argues that the mere generic statement of the possibility of cleavable fusion

Page 1004

expression, along with the DNA sequence encoding hGH, a single enzyme (trypsin) for cleaving undisclosed conjugate proteins, and a statement of that enzyme's cleavage sites as being potential amino acid extensions conjugated to hGH is not an enabling disclosure commensurate in scope with the claim. Genentech responds that all of the district court's factual findings regarding enablement are supported by the record. More specifically, Genentech argues that those skilled in the art of recombinant protein expression and purification at the time of filing, July 5, 1979, would have been able to use cleavable fusion expression to produce hGH without undue experimentation by using the teachings of the specification along with methods and tools well known in the art. We conclude that Novo has raised more than a substantial question concerning the validity of the '199 patent. In fact, it has shown that the patent is invalid.

Section Section 112, Para. 1, provides, in relevant part that:

> [t]he specification shall contain a written description of the invention, and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same. . . .

" [T]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.' " *In re Wright* , 999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed.Cir. 1993); *see also Amgen Inc. v. Chugai Pharms. Co.* , 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed.Cir. 1991); *In re Fisher* , 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970) (" [T]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art."). Whether making and using the invention would have required undue experimentation, and thus whether the disclosure is enabling, is a legal conclusion based upon several underlying factual inquiries. *See In re Wands* , 858 F.2d 731, 735, 736-37, 8 USPQ2d 1400, 1402, 1404 (Fed.Cir. 1988).

[1] The question before us is whether the specification would have enabled a person having ordinary skill in the art at the time of filing to use cleavable fusion expression to make hGH without undue experimentation. There is no dispute that the portion of the specification chiefly relied upon by Genentech and by the district court, column 7, lines 29-59, does not describe in any detail whatsoever how to make hGH using cleavable fusion expression. For example, no reaction conditions for the steps needed to produce hGH are provided; no description of any specific cleavable conjugate protein appears. The relevant portion of the specification merely describes three (or perhaps four) applications for which cleavable fusion expression is *generally* well-suited and then names an enzyme that might be used as a cleavage agent (trypsin), along with sites at which it cleaves ("arg-arg or lys-lys, etc."). [3] Thus, the specification does not describe a specific material to be cleaved or any reaction conditions under which cleavable fusion expression would work.

[3] At column 7, lines 52-58, the specification states: "At least in the latter three applications [of

> the four applications that are disclosed], the synthetic adaptor molecular [sic] employed to complete the coding sequence of the mRNA transcript can additionally incorporate codons for amino acid sequences specifically cleavable, as by enzymatic action. For example, trypsin will cleave specifically at arg-arg or lys-lys, etc."

Notwithstanding this limited disclosure, Genentech argues (and the district court found) that those of ordinary skill in the art would have been able to practice the claimed invention without undue experimentation. Essentially, Genentech's argument is that the knowledge of one skilled in the art was sufficient to provide all of the missing information and, more specifically, that the disclosure of a DNA encoding hGH, when combined with prior art cleavable fusion expression techniques applied to non-human proteins, would enable the practice of the claimed method. In support of this argument, Genentech points to the testimony of Dr. Ravetch, who testified as to the knowledge of one skilled in the art, to the extensive description of enzymes in the reference textbook *Methods in Enzymology* , and to the specification's explicit reference to British Patent 2008123-A, which more fully details the potential use of trypsin in cleavable fusion expression.

In response to these arguments, Novo asserts that at the time of filing, trypsin and other like enzymes were used only to digest proteins, not to specifically and precisely cleave conjugate proteins to yield intact, useful proteins, and that the British patent explicitly indicates that trypsin would not be useful for the cleavable fusion expression of arginine-containing proteins such as hGH. Novo further argues that neither the specification nor the references cited by Genentech suggest a single amino acid sequence, out of the virtually infinite range of possibilities,

Page 1005

that would yield hGH in a useful form when cleaved from the conjugate protein.

We agree with Novo. Genentech's arguments, focused almost exclusively on the level of skill in the art, ignore the essence of the enablement requirement. Patent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable. *See Brenner v. Manson* , 383 U.S. 519, 536, 148 USPQ 689, 696 (1966) (stating, in context of the utility requirement, that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.") Tossing out the mere germ of an idea does not constitute enabling disclosure. While every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention. That requirement has not been met in this specification with respect to the cleavable fusion expression of hGH.

[2] It is true, as Genentech argues, that a specification need not disclose what is well known in the art. *See , e.g. , Hybritech Inc. v. Monoclonal Antibodies, Inc.* , 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed.Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement. However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement. This specification provides only a starting point, a direction for further research.

[3] The specification indicates that it purports to solve a problem. That problem is summarized at column 3, line 65, through column 4, line 8:

> [A] need has existed for new methods of producing hGH and other polypeptide products in quantity and that need has been particularly acute in the case of polypeptides too large to admit to organic synthesis or, for that matter, microbial expression from entirely synthetic genes. Expression of mammalian hormones from mRNA transcripts . . . has permitted only microbial production of bio-inactive conjugates from which the desired hormone could not practically be cleaved.

The problem thus was the difficulty of obtaining hGH from a precursor containing added protein material. This problem was solved by the description of a method of obtaining hGH unaccompanied by a leader sequence or other extraneous proteins, as claimed in the '980 patent.

However, the specification for the '199 patent, which is the same as the specification for the '980 patent, does not provide a specific enabling disclosure concerning what the new claim recites, *viz.* , obtaining hGH by cleaving an hGH-containing conjugate protein. That was the problem avoided by the invention claimed in the '980 patent. The present specification contains no more disclosure than the '980 specification, but this patent now purports to claim the unresolved problem that the '980 patent overcame. Genentech is attempting to bootstrap a vague statement of a problem into an enabling disclosure sufficient to dominate someone else's solution of the problem. This it cannot do.

Genentech's arguments in favor of enablement are unavailing. While Genentech's witness, Dr. Ravetch, did state that it would have been possible for a skilled artisan to create a DNA sequence coding for arg- arg-hGH or lys-lys-hGH, he did not discuss the experimentation needed for the creation of DNA coding for more extensive sequences, such as those that have proved necessary to the production of hGH via cleavable fusion expression. Likewise, the description of a wide range of enzymes in *Methods in Enzymology* , by itself, does not render routine the determination of an enzyme-conjugate protein combination. Rather, as Novo argues and the record reflects, various combinations of conjugate protein sequences, cleaving enzymes, and reaction conditions needed to be studied to establish a process for producing hGH in useful form. Finally, the British patent cited in the specification actually works against Genentech's position by explicitly teaching that trypsin would not work well to produce hGH. The specification does not even acknowledge any of the known difficulties associated with using trypsin on an hGH conjugate protein. This specification is so lacking with respect to the limitation of paragraph (b) of claim 1 that providing testimony regarding the skill in the art has been an exercise in futility.

[4] The limited testimony regarding the knowledge of one skilled in the art offered by

Page 1006

Genentech at the preliminary injunction hearing, and relied upon by the district court, is further undermined by the fact that no one had been able to produce *any* human protein via cleavable fusion expression as of the application date. If, as Genentech argues, one skilled in the art, armed only with what the patent specification discloses (a DNA sequence encoding a human protein, in this case, hGH, and a single example of an enzyme and its cleavage site), could have used cleavable fusion expression to make a human protein without undue experimentation, it is remarkable that this method was not used to make any human protein for nearly a year, *see* Shine *et al.* , 285 Nature 456 (June 1980), or to make hGH for five years. *See* Belagaje *et al.* , 3 DNA 120 (1984). Certainly, DNAs encoding desirable human proteins were known at the time of filing (*e.g.* , insulin, described in the British patent), and a great many researchers were attempting to produce human proteins using recombinant DNA technology. This failure of skilled scientists, who were supplied with the teachings that Genentech asserts were sufficient and who were clearly motivated to produce human proteins, indicates that producing hGH via cleavable fusion expression was not then within the skill of the art. The contrary testimony offered by Genentech's witnesses, who hypothesized about the skill of the art more than fifteen years earlier, does not demonstrate the incorrectness of Novo's arguments. *See In re Buchner* , 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed.Cir. 1991) ("[A]n expert's opinion on the ultimate legal issue [of enablement] must be supported by something more than a conclusory statement.").

Moreover, it stands to reason that if the disclosure of a useful conjugate protein and the method for its cleavage were so clearly within the skill of the art, it would have been expressly disclosed in the specification, and in the usual detail. Patent draftsmen are not loath to provide actual or constructive examples, with details, concerning how to make what they wish to claim. In addition, as indicated above, the specification of this patent was clearly drafted to claim the invention of obtaining hGH *unaccompanied by* extraneous protein, the cleavage of which was identified by the specification as a problem in this field. Genentech's inventors knew how to enable that which they had invented. These facts underline the inadequacy of the specification in enabling that which it provided only a means to avoid.

The record does not support the district court's implicit finding that the disclosure of trypsin and its cleavage site enables the production of any conjugate protein from which hGH can practically be cleaved and thus produced in useful form; the record indicates that determination of these features required further undue experimentation. None of the expert testimony relied upon by Genentech or by the district court suggests otherwise. [4] Where, as here, the claimed invention is the application of an unpredictable technology in the early stages of development, an enabling description in the specification must provide those skilled in the art with a specific and useful teaching. Genentech has

not shown that the '199 patent provides that teaching.

[4] Novo's witness, Dr. Villa-Komaroff, merely stated on cross-examination that, assuming arg- arg-hGH was initially produced and successfully extracted from the transformed cell, that " [u]nder the best condition, approximately five percent of the time there will be in the [post-digestion] mix [hGH]." This statement, characterized by Genentech as an admission, was made in the limited context of partial trypsin digests of isolated arg-arg-hGH, but none of the necessary experimentation is described in the specification, which is where it should be if it is to contribute to an enabling disclosure.

Under the circumstances, we are compelled to conclude that the district court made an error of law in ruling that Genentech showed a likelihood of success on enablement. *See In re Epstein* , 32 F.3d 1559, 1568, 31 USPQ2d 1817, 1823 (Fed.Cir. 1994) (" [E]nablement is a question of law . . . which may involve subsidiary questions of fact."). Furthermore, since we are able to review the record and to read the specification, there is no reason why we should limit our decision here to reversing the grant of the preliminary injunction. Rather, because the parties agreed at oral argument that the enablement issue had been thoroughly ventilated by the extensive arguments before the district court and that court's extensive analysis, [5] we deem it appropriate to rule on the

Page 1007

merits of Novo's defense of invalidity. *See* 28 U.S.C. Section 2106 (1994) ("The Supreme Court or any other court of appellate jurisdiction may . . . direct the entry of such appropriate judgment, decree, or order, or require such further proceedings to be had as may be just under the circumstances."); *Chicago Observer, Inc. v. City of Chicago* , 929 F.2d 325, 329 (7th Cir. 1991) (reversing preliminary injunction and instructing district court to enter judgment in favor of defendant because the plaintiff "has not suggested that it holds more evidence it could offer at trial and we cannot imagine what additional evidence could aid its cause. Litigation is costly not only for the litigants but also for parties in other cases waiting in the queue for judicial attention. Once it becomes clear that additional proceedings are pointless, the court should bring the case to a close."). We therefore hold that claim 1 and hence the '199 patent are invalid as a matter of law for failure of the specification to enable the practice of the claimed method.

[5] Genentech stated that it would introduce new evidence at a full trial only in response to new arguments and new defenses raised by Novo. Novo revealed that it had no intention of raising any new arguments or defenses, stating that the "full and complete record" on appeal gave this court "the benefit of everything it really needs" to reach ultimate issues of validity. Thus, considerations that would normally dictate that we limit our decision to reversing the grant of the preliminary injunction are not present. *See University of Texas v. Camenisch* , 451 U.S. 390, 395 (1981) (stating that it is generally inappropriate to render a final judgment on the merits at the preliminary injunction stage because "a preliminary injunction is customarily granted on the basis of procedures that are less formal and *evidence that is less complete than in a trial on the merits* .") (citations omitted) (emphasis added).

Novo has also *argued* that the '199 patent is invalid for lack of a written description of the claimed invention and that it is not infringed by Novo. Given our decision on the enablement question, we need not reach these issues.

B. *Other Factors*

Novo also challenges the district court's findings that irreparable harm, the equities, and the public interest favored Genentech. In view of our conclusion concerning the invalidity of the '199 patent, we need not consider these other findings.

CONCLUSION

The court abused its discretion by granting the preliminary injunction based upon an error of law. The district court's error was in finding that Genentech had shown a likelihood of success on the merits since the '199 patent is invalid for failure of the specification to meet the enablement requirement of Section 112, Para. 1. Accordingly, we vacate the injunction and instruct the district court to dismiss Genentech's claim for infringement of the '199 patent on the ground that the patent is invalid. *VACATED* .

- End of Case -

ISSN 1526-8535

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > U.S. v. Telectronics Inc., 1217 (Fed. Cir. 1988)

8 USPQ2d 1217

U.S. v. Telectronics Inc.

U.S. Court of Appeals Federal Circuit

Nos. 87-1445, -1446

Decided September 22, 1988

857 F2d 778

Headnotes

PATENTS

[1] Patent construction -- Claims -- Broad or narrow (► 125.1303)

Federal district court erred in interpreting claim for bone growth stimulator device by limiting claim to non-implanted anodes and excluding anodes implanted adjacent to bone and by basing interpretation on claim language which cautions against formation of "fibrous tissue" around anode, since such language is not determinative of anode placement.

[2] Patent construction -- Claims -- Broad or narrow (► 125.1303)

Doctrine of claim differentiation presumes difference in meaning and scope when different words or phrases are used in separate claims, and thus federal district court erroneously construed claim of bone healing invention so that its limitations are same as dependent claim.

[3] Infringement -- Literal infringement (► 120.05)

Determination that claims for patented bone growth stimulator device, as properly construed, encompass both skin anode and implanted anode warrants finding of literal infringement by defendant's device, in view of defendant's admission that literal infringement is avoided only if patented device's claims are construed to be limited to skin anode.

[4] Patentability/Validity -- Adequacy of disclosure (► 115.12)

Patent infringement defendant which seeks to prove invalidity based upon non-enablement must show facts, supported by clear and convincing evidence, demonstrating that patent was not enabling, and federal district court findings that claims for patented bone growth stimulator device are not limited to specific metal/current combination, and that determination of optimal electrical current for materials other than stainless steel would require dose response study and would involve "undue amount of experimentation," are insufficient to establish clear and convincing proof of invalidity, since time and cost of such studies do not, standing alone, show experimentation to be excessive.

Particular Patents

Particular patents -- General and mechanical -- Medical healing device

3,842,841, Brighton, Friedenberg, and Redka, constant current power pack for expediting healing of bone fracture and bone defects in living beings, including means of internal implant, and method of using device, valid and infringed.

Case History and Disposition

Appeal from the U.S. District Court for the District of Colorado, Matsch, J; 3 USPQ2d 1571 .

Page 1218

Patent infringement action brought by U.S. and Zimmer Inc., as involuntary plaintiff, against Telectronics Inc. and BGS Medical Inc. From federal district court's judgment holding that defendants did not infringe, that patent is not invalid under 35 USC 112, and holding that defendant Telectronics is not entitled to attorney's fees, parties cross-appeal. Affirmed in part and *reversed* in part.

Attorneys

John Fargo (Richard K. Willard, assistant attorney general and Vito J. DiPietro, with him on brief), Department of Justice, for plaintiff/appellant.

Michael I. Rackman, of Gottlieb, Rackman & Reisman, New York, N.Y. (Barry A. Cooper and Jeffrey M. Kaden, New York, and William C. Nealon, Suffield, Conn., with him on brief), for defendants/counterclaim-plaintiffs/cross-appellants.

Judge

Before Newman, Archer, and Mayer, circuit judges.

Opinion Text

Opinion By:

Archer, J.

The United States of America (government) appeals the judgment of the United States District Court for the District of Colorado in *United States v. Telectronics, Inc* ., 658 F.Supp. 579, 3 USPQ2d 1571 (D. Colo. 1987), holding that Telectronics, Inc. and BGS Medical, Inc. (Telectronics) do not infringe U.S. Patent No. 3,842,841 ('841). Telectronics cross-appeals the determinations that the '841 patent is not invalid under 35 U.S.C. §112 (1982) and that Telectronics is not entitled to attorney fees under 35 U.S.C. §285 (1982). [1] We reverse the district court's holding that the '841 patent is not infringed by Telectronics. The determinations that the patent is not invalid under section 112 and that Telectronics is not entitled to attorney fees are *affirmed*.

[1] Telectronics has not appealed the district court's holdings on other issues it raised below.

Background

The '841 patent issued to Carl T. Brighton, et al. and was assigned to the United States. The patent resulted from work under contract between the Office of Naval Research and the University of Pennsylvania, where the inventors were employed. 658 F.Supp. at 581, 3 USPQ2d at 1571. The '841 patent is directed to a bone growth stimulator device for speeding the healing of fractures and other bone defects. The accused devices of Telectronics are marketed under the name OSTEOSTIM and include Model 2000 and earlier models S-12, HS-12 and XM-12. Zimmer, Inc. (Zimmer), a licensee of the government under the '841 patent, also markets a bone growth stimulator which the district court found to be "quite similar to the preferred embodiment of the invention shown in the patent." 658 F.Supp. at 581, 3 USPQ2d at 1571.

Normally bone fractures heal naturally as a result of the body's own reparative process. Approximately five percent of the time, however, natural healing does not occur and bone grafting is conventionally employed to attempt to stimulate further reparative growth. 658 F.Supp. at 581-82, 3 USPQ2d at 1572.

Bone growth stimulators are particularly useful in the treatment of fractures normally requiring grafting. The success rate is at least as great as with grafting and the procedure results in less discomfort to the patient. 658 F.Supp. at 582, 3 USPQ2d at 1572. Bone growth stimulators expedite the healing of a fracture or bone defect by passing a low level constant direct current to the site of the fracture via a cathode placed internally at the site of the fracture. *Id* . The placement of the circuit-completing anode is at issue in this case.

The claim of the '841 patent at issue reads:

> 1. A system for expediting the healing of bone fractures and bone defects in a living being comprising:
>
> constant current source means for providing a constant value of current despite changes in load;
>
> means for connecting said constant current means to the living being, such connection acting to produce current flow into said fracture or defect,
>
> said connecting means including further means for application internally of said living being at the fracture or defect site,
>
> said constant current being a selected value within a predetermined microampere range so as to promote bone formation at the fracture or bone defect site and avoid fibrous tissue formation in other areas of the living being.

In describing the operation of the patented invention and the accused devices, the district court stated that

> hen using the product of either party, the cathode (negative terminal) is placed in the defect site. The Zimmer cathode is made of stainless steel, the material described in the patent. The OSTEOSTIM cathode is made of titanium. The major
>
> **Page 1219**
>
> difference between the products of the parties pertains to the anode (positive terminal). As disclosed in the patent drawing and accompanying description, and as marketed by Zimmer, the anode is placed on the skin of the patient. So is the power pack (current source) itself. The only internal element [in Zimmer] is the cathode -- a pin which is inserted through the skin into the defect site. This technique avoids the need for surgery; after several months of treatment, the cathode pin is simply pulled out. The OSTEOSTIM device, on the other hand, is completely implanted, an embodiment which while not shown in the patent drawing is nevertheless described. The power pack and the anode of the OSTEOSTIM are placed in soft tissue near the bone. The original OSTEOSTIM S-12 had a power pack from which two wires extended, the wires terminating respectively at a titanium cathode for placement in the defect site, and a platinum anode for placement in the soft tissue. In all of the later models, including the OSTEOSTIM-2000, the anode wire was omitted. The anode is the case itself -- titanium with a patch of platinum.

658 F.Supp. at 582, 3 USPQ2d at 1572.

Because the Telectronics devices have an implanted anode, the district court stated that "the critical question in the case is whether the language of claim 1 (and with it, the dependent claims) is limited to a skin anode." 658 F.Supp. at 583, 3 USPQ2d at 1573. Telectronics contended before the district court that "an internal anode could not come within the literal language of claim 1 because fibrous tissue formation inevitably results from such an implant." *Id* . In finding no literal infringement, the district court held with respect to the accused device that

> fibrous tissue formation could not be avoided in the dictionary sense of "keep away from" or "stay clear of".
>
> The claim limitation directed to the avoidance of fibrous tissue means what it plainly says. Accordingly, there is no literal infringement because in the context of the patent, even minimal fibrous tissue formation is not its avoidance. *Id* .

The district court also held that the '841 patent was not infringed under the doctrine of equivalents on the basis that the prosecution history established that the patentees, in responding to rejections by the examiner, repeatedly represented that the invention was limited to a surface or skin. anode. After examining the prosecution history in detail, the district court stated: "[i]t is clear from the file history that what convinced the Examiner to allow the claims over the prior art was the argument that a skin anode was used in the invention." 658 F.Supp. at 587, 3 USPQ2d at 1576.

On appeal, the government contends that the district court in its literal infringement analysis erred as a matter of law in its claim interpretation. According to the government, the claim limitation read as a whole requires the constant current supply to be controlled in a manner to minimize the amount of fibrous tissue formed. Telectronics counters that the district court properly interpreted the claim

phrase "avoid fibrous tissue formation" and the prosecution history to find that the claim is limited to the use of a skin anode.

1. *Claim Interpretation*

A. Analysis of literal infringement involves two inquiries: first the claims must be properly construed to determine their scope and then it must be determined whether the properly interpreted claims encompass the accused structure. *ZMI Corp. v. Cardiac Resuscitator Corp* ., 844 F.2d 1576, 1578, 6 USPQ2d 1557, 1559 (Fed.Cir. 1988). Claim construction is reviewed as a matter of law. However, interpretation of a claim may depend on evidentiary material about which there is a factual dispute, requiring resolution of factual issues as a basis for interpretation of the claim. *Uniroyal, Inc. v. Rudkin-Wiley Corp* ., 837 F.2d 1044, 1054, 5 USPQ2d 1434, 1441 (Fed.Cir. 1988). In interpreting claims resort should be made to the claims at issue, the specification, and the prosecution history. *Loctite Corp. v. Ultraseal Ltd* ., 781 F.2d 861, 867, 228 USPQ 90, 93 (Fed.Cir. 1985). The question of literal infringement is a factual inquiry and is reviewed on a clearly erroneous standard. *Loctite Corp* ., 781 F.2d at 866, 228 USPQ at 93.

B. The district court interpreted the phrase "avoid fibrous tissue formation" as precluding the use of an implanted anode, and thus limiting the claim to a surface or skin anode. To the court, the word "avoid" based on its dictionary definition meant that there could be no fibrous tissue. Because an implanted anode inevitably resulted in some fibrous tissue, the court determined that this placement of the anode was not covered by the claim language.

The government argues that the district court erred in its interpretation because the phrase at issue was not read in context. It contends that the claim language read as a whole only requires that there be avoidance

Page 1220

or minimization of fibrous tissue formation by controlling or selecting the current. Thus, any fibrous tissue that may result from the implantation of the anode is immaterial.

[1] We agree that the district court erred in its interpretation of the limitation of claim 1 and in its conclusion that such language is determinative of the anode placement. In the claim, constant current is a "selected value . . . so as to promote bone formation . . . and avoid fibrous tissue formation in other areas." Nothing in this language relates to fibrous tissue that may be formed from implantation of an anode. The plain meaning of the disputed language is only that current related fibrous tissue formation is to be avoided.

In considering other sources for interpretation of claims, we note that the specification supports the plain meaning of the clause at issue. *See Autogiro Co. of America v. United States* , 384 F.2d 391, 397, 155 USPQ 697, 702-03 (Ct.Cl. 1967) ("[p]atent law allows the inventor to be his own lexicographer. . . . [t]he specification aids in ascertaining the scope and meaning of the language employed in the claims inasmuch as words must be used in the same way in both the claims and the specification.") The specification makes no mention of whether a skin anode or an implanted anode may cause or deter the formation of fibrous tissue. There is, however, a discussion of the increase or decrease in fibrous tissue that is formed with varying currents. Further, we find nothing in the prosecution history that would indicate that fibrous tissue resulting from implantation of an electrode was at issue or was intended to be covered by the claim language.

The claim language relied on by the district court is, therefore, not determinative of anode placement and does not require that claim 1 be limited to a surface or skin anode.

C. Claim 1 recites a "means for connecting said constant current means to the living being, such connection acting to produce current flow into said fracture or defect." Since this recitation is in the "means plus function" format permitted by 35 U.S.C. §112, ¶6, it must be interpreted to cover the structure disclosed in the specification and the equivalents thereof. *See D.M.I. Inc. v. Deere & Co* ., 755 F.2d 1570, 1575, 225 USPQ 236, 239 (Fed.Cir. 1985).

"In construing a 'means plus function' claim, as also other types of claims, a number of factors may be considered, including the language of the claim, the patent specification, the prosecution history of the patent, other claims in the patent, and expert testimony [citations omitted]. Once such factors are weighed, the scope of the 'means' claim may be determined." *Palumbo v. Don-Joy Co* ., 762 F.2d 969,

975, 226 USPQ 5, 8 (Fed.Cir. 1985); *see also Moeller v. Ionetics Inc .*, 794 F.2d 653, 656, 229 USPQ 992, 994 (Fed.Cir. 1986) (resort to extrinsic evidence, such as the prosecution history, is necessary to interpret disputed claims); *SSIH Equip. S.A. v. U.S. Int'l Trade Comm'n* , 718 F.2d 365, 376, 218 USPQ 678, 688 (Fed.Cir. 1983) (the prosecution history is always relevant to proper claim interpretation). "[T]he prosecution history (or file wrapper) limits the interpretation of claims so as to exclude any interpretation that may have been disclaimed or disavowed during prosecution in order to obtain claim allowance." *Standard Oil Co. v. American Cyanamid Co .*, 774 F.2d 448, 452, 227 USPQ 293, 296 (Fed.Cir. 1985); *see also McGill Inc. v. John Zink Co .*, 736 F.2d 666, 673, 221 USPQ 944, 949 (Fed.Cir.), cert. denied , 469 U.S. 1037 (1984).

The district court found that both implanted and surface anodes are disclosed in the specification of the '841 patent. The specification provides: "[a]lthough the cathode must be placed in the fracture . . . the anode, though described as preferably being placed on the remote side of the site from the cathode, may be placed anywhere so long as it completes a circuit with the cathode." Elsewhere the specification provides that "[i]f the anode is to be implanted, it . . . is bared of its cover." Thus, unless other relevant claim interpretation factors clearly require a different construction, the plain language of claim 1 and the specification cover an implanted anode as well as a skin or surface anode.

In its claim construction and literal infringement analysis, the district court did not consider the prosecution history but concluded for the reasons indicated in I.A., *supra* , that a surface anode was required. The prosecution history, however, was extensively discussed in the court's consideration of the doctrine of equivalents.

Prior to allowance, the applicants communicated with the examiner six times. These communications are referred to as "A" through "F" in the district court's opinion and herein. The district court concluded that because of the prosecution history appellant is "prevented from construing its claims to include an internal anode." 658 F.Supp. at 587, 3 USPQ2d at 1577. We disagree.

The district court first relied on Amendments B and C. In the former, applicants inserted the limitation "only one of said connecting means applied to the skin surface of the living being" for the purpose of at

Page 1221

tempting to overcome a prior art rejection. This amendment was accompanied by remarks to the same effect. In Amendment C, this limitation was *argued* to be a distinguishing feature of the invention. Applicants' attempts to distinguish over the prior art in this fashion were unsuccessful, and the claims were later amended to remove this recitation. The arguments emphasizing the use of a skin electrode, which were made at the time the application claims explicitly contained such a limitation, cannot furnish a basis for restricting issued claim 1, which lacks any such limitation. *See Smith v. Snow* , 294 U.S. 1, 16 (1935) ("It is of no moment that in the course of the proceedings in the Patent Office the rejection of narrow claims was followed by the allowance of the broader Claim 1."); *Kistler Instrumente AG v. United States* , 628 F.2d 1303, 1308, 211 USPQ 920 (Ct.Cl. 1980) (*aff'g* and adopting 203 USPQ 511, 511) (courts are not permitted to read "back into the claims limitations which were originally there and were removed during prosecution of the application through the Patent Office.")

In Amendment D a claim which ultimately issued as independent claim 1 was submitted for the first time. In holding claim 1 should be limited to a skin anode, the district court relied on Amendments E and F which contained arguments relative to a skin anode and which were held by the district court to be in support of the claims that finally issued. [2] From Amendment F the district court quoted the following language:

[2] There was some uncertainty as to which set of claims certain of these remarks applied, but the district court found that Amendments E and F related to the claims presented in Amendment D. Because we conclude that the district court erroneously limited the claims even if the remarks in controversy did apply to the claims which issued, we need not determine whether the district court correctly resolved this dispute.

> Applicants take strong exception to [the examiner's] analysis of the [Friedenberg-Kohanim article]. Nowhere in this article is there either stated or suggested that one of the electrodes need simply be applied to the surface and the other introduced into the fracture

site.

These remarks were submitted to correct the examiner's characterization of a prior art reference (an article written by one of the co-inventors of the patented invention). The examiner's characterization of the reference was made in rejecting claims, at least some of which included an explicit recitation of a surface anode. Thus, these remarks are of little significance.

The district court also noted the following argument in Amendment F:

> Applicants throughout the prosecution of this case have repeatedly attempted to convey to the Examiner the important differences between their technique where only one of the electrodes need pierce the skin *and enter the fracture site* and the other prior art arrangements where two electrodes have to pierce the skin *and then fit into prescribed locations formed in the bone structure* under study. (Emphasis added.)

The quoted language does not mean that one electrode must remain on the surface of the skin. Rather, as applicants argue, it means that both of their electrodes do not have to be placed in the bone structure itself. The district court erred in construing the phrase "only one of the electrodes need pierce the skin" to mean that the other electrode must remain on the surface. This phrase, when read in conjunction with the words that follow -- "and enter the fracture site" -- only serves to distinguish prior art where both electrodes were placed in the bone structure. [3] The entire emphasis of the prior art article was that the electrodes were placed in the bone for the purpose of attempting to lengthen the bone. The article was not concerned with the healing of fractures or bone defects. In the healing of fractures, it is not necessary (or desirable) to place both electrodes in the bone.

---

[3] The district court recognized that "[t]here are three possible positions for placement of the anode: on the skin, in soft tissue, and in the bone. Placement within the bone must be done carefully to avoid the effect of insulation from the cortical bone." 658 F.Supp. at 583, 3 USPQ2d at 1573.

---

[2] D. "There is presumed to be a difference in meaning and scope when different words or phrases are used in separate claims. To the extent that the absence of such difference in meaning and scope would make a claim superfluous, the doctrine of claim differentiation states the presumption that the difference between claims is significant." *Tandon Corp. v. United States Int'l Trade Comm'n* , 831 F.2d 1017, 1023, 4 USPQ2d 1283, 1288 (Fed.Cir. 1987). "Where some claims are broad and others narrow, the narrow claim limitations cannot be read into the broad whether to avoid invalidity or to escape infringement. *Uniroyal, Inc* ., 837 F.2d at 1054-55, 5 USPQ2d at 1441 (quoting *D.M.I., Inc. v. Deere & Co* ., 755 F.2d at 1574, 225 USPQ at 239.

In this case the district court erroneously construed claim 1 so that its limitations are

Page 1222

the same as dependent claim 2. Claim 2 reads in its entirety: "The system as defined in claim 1 wherein said connecting means includes means for external application to the skin surface, the internal means being a cathodic electrode, the external means being an anodic electrode." The doctrine of claim differentiation, therefore, counsels against limiting claim 1 to the use of a skin anode. *See D.M.I., Inc* ., 755 F.2d at 1574, 225 USPQ at 239.

E. On the basis of the above analysis, we conclude that the district court erred as a matter of law in its interpretation of claim 1 of the '841 patent. *Fromson v. Advance Offset Plate, Inc* ., 720 F.2d 1565, 1569, 219 USPQ 1137, 1140 (Fed.Cir. 1983).

The ordinary and accustomed meaning of claim 1 is that the current should be applied so as to avoid the formation of fibrous tissue. In support of this means plus function claim, the specification of the '841 patent disclosed both an implanted and a surface anode structure. The other claims, the specification and the prosecution history do not require a narrower construction. Thus, the district court erred in limiting claim 1 to the use of a skin anode.

II. *Literal Infringement*

The question of literal infringement is a factual inquiry. *Uniroyal, Inc. v. Rudkin-Wiley Corp* ., 837 F.2d at 1054, 5 USPQ2d at 1441. Literal infringement requires that every limitation of the patent claim must be found in the accused device. *Mannesmann Demag Corp. v. Engineered Metal Prods. Co* ., 793

F.2d 1279, 1282, 230 USPQ 45, 46 (Fed.Cir. 1986). In this case, the findings of the district court establish literal infringement and, thus, there is no need to remand for a determination of the factual question of infringement under properly interpreted claims.

[3] The district court stated in its opinion that:

> The defendant's denial of infringement in this case is based solely on the defendants' anode and case being used internally. Accordingly the critical question in the case is whether the language of claim 1 (and with it the dependent claims) is limited to a skin anode.

As we have held in I., *supra* , the properly construed claims encompass both a skin anode and an implanted anode. The district court erroneously limited the claims of the '841 patent to a surface anode. Accordingly, on the position of Telectronics as stated by the district court, literal infringement is established.

The government also challenges the district court's finding of no infringement under the doctrine of equivalents. Because the accused devices literally infringe, a doctrine of equivalents inquiry is unnecessary. *See ZMI Corp. v. Cardiac Resuscitator Corp .*, 844 F.2d at 1581, 6 USPQ2d at 1562 ("When literal infringement is not found, the equitable doctrine of equivalents comes into play.").

III. *Invalidity*

The district court held: "[i]f claim 1 were to be given the broad meaning which plaintiff asserts, then the patent would be invalid for a failure to comply with the specification requirements of 35 U.S.C. §112." 658 F.Supp. at 589, 3 USPQ2d at 1577-78. According to the district court a dose response study must be performed for materials other than stainless steel to determine the optimal electrical current to be supplied and this would involve "an undue amount of experimentation." *Id* .

In its cross-appeal Telectronics argues that the patent is invalid for non-enablement regardless of how the claims are interpreted because the disclosure does not bear a reasonable relationship to the scope of the claims.

Enablement is a legal determination which is reviewed as a matter of law. *Raytheon Co. v. Roper Corp* ., 724 F.2d 951, 951-60, 220 USPQ 592, 599 (Fed.Cir. 1983). To be enabling under section 112, the patent must contain a description sufficient to enable one skilled in the art to make and use the claimed invention. *Id* . A patent may be enabling even though some experimentation is necessary; the amount of experimentation, however, must not be unduly extensive. *Atlas Powder Co. v. E.I. du Pont De Nemours & Co* ., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed.Cir. 1984). A patent is presumed valid, and the burden of proving invalidity, whether under section 112 or otherwise, rests with the challenger. Invalidity must be proven by facts supported by clear and convincing evidence. *Ralston Purina Co. v. Far-Mar-Co., Inc* ., 772 F.2d 1570, 1573-74, 227 USPQ 177, 178 (Fed.Cir. 1985) ("A party asserting invalidity based on 35 U.S.C. §112 bears no less a burden . . . than any other patent challenger.") Thus, although not mentioned by the district court it is Telectronics' burden to show by facts supported by clear' and convincing evidence that the patent was not enabling.

We note first that Telectronics admits that "[t]he patent *does* disclose how to successfully practice the invention -- if stainless

Page 1223

steel electrodes and a current in the range of 5-20 microamperes is [sic] used." (Emphasis in original.) Lack of enablement is asserted on the basis that "the claims are not limited to the specific metal/current combination."

The district court thought that to determine the optimal electrical current for materials other than stainless steel a dose response study would be required and that this would involve an "undue amount of experimentation." The district court said "the patent does not tell a person reasonably skilled in the art how to make and use this invention because it fails to teach how to select a level of current to promote bone formation and avoid fibrous tissue . . . formation from such current" for electrodes made of materials other than stainless steel. 658 F.Supp. at 589, 3 USPQ2d at 1578. It noted that "the patent does not contain an adequate description of the methodology for a dose response study for any cathode material other than stainless steel" and that "only those who were expert in the field and actually working with bone, doing electrical stimulation experiments . . . would know how to

conduct" such a study. Moreover, the district court thought that the time and expense of such a study also indicated undue experimentation would be required.

[4] We are convinced that these findings and conclusions are insufficient to constitute clear and convincing proof of invalidity. First, it is undisputed that the patent disclosures are enabling with respect to stainless steel electrodes, with the range of current for such electrode set out in the specification. The specification shows this range of current was obtained by a dose response test. Next, according to the district court "those who were expert in the field and actually working with bone, doing electrical stimulation experiments . . . would know how to conduct a dose response study to determine the appropriate current to be used with other materials as electrodes." *Id* . The appropriate levels of current for other electrodes to promote bone growth and avoid fibrous tissue could, therefore, be determined. Finally, the emphasis by the district court on the time and cost of such studies is misplaced. While these factors may be taken into account, in the circumstances of this case we are unpersuaded that standing alone they show the experimentation to be excessive. The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *Hybritech Inc. v. Monoclonal Antibodies, Inc* ., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed.Cir. 1986), cert. denied , 107 S.Ct. 1606 (1987).

Since one embodiment is admittedly disclosed in the specification, along with the general manner in which its current range was ascertained, we are convinced that other permutations of the invention could be practiced by those skilled in the art without undue experimentation. *See SRI Int'l v. Matsushita Elec. Corp. of America* , 775 F.2d 1107, 1121, 227 USPQ 577, 586 (Fed.Cir. 1985) (the law does not require an applicant to describe in his specification every conceivable embodiment of the invention); *Hybritech Inc* ., 802 F.2d at 1384, 231 USPQ at 94 (the enablement requirement may be satisfied even though some experimentation is required). While perhaps fortuitous, as the district court found, the OSTEOSTIM device of Telectronics used a current level of 20 microamperes, within the "substantially 5 microamperes to substantially 20 microamperes" range set forth in claim 5 and disclosed in the specification.

The district court also held that if claim 1 is read to mean that the current must be applied so as to minimize fibrous tissue formation then it would be invalid under 35 U.S.C. §112 (1982) because it would be "impossible to determine when sufficient minimization takes place to determine what current range is involved." 658 F.Supp. at 589, 3 USPQ2d at 1578. The district court erred as a matter of law in this holding. *Shatterproof Glass Corp. v. Libby-Owens Ford Co* ., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed.Cir.), cert. dismissed , 106 S.Ct. 340 (1985). Section 112, ¶2, requires only reasonable precision in delineating the bounds of the claimed invention. *Id* . Adjusting current so as to minimize fibrous tissue formation in other parts of the living being reasonably apprises those skilled in the art of the bounds of the claimed invention and is as precise as the subject matter permits. *See id* . Thus, we hold as a matter of law that the '841 patent is enabling and that the claims satisfy 35 U.S.C. §112, ¶2.

In its cross appeal, Telectronics argues that the specification is enabling only for the use of stainless steel while the claims are not limited in the types of material from which the electrodes can be made. It contends that the scope of the protection must bear a reasonable relationship to the scope of enablement, citing *In re Fisher* , 427 F.2d 833, 838-39, 166 USPQ 18, 23-24 (CCPA 1970) ("In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved."),

Page 1224

and *In re Bowen* , 492 F.2d 859, 861-64, 181 USPQ 48, 50-52 (CCPA 1974) (section 112 requires that the scope of claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art). *Fisher* and *Bowen* both involved chemical reactions, recognized by our predecessor court as having a high degree of unpredictability and therefore requiring an increased enablement disclosure. Yet, in *Bowen* the board's non-enablement rejection was *reversed* where the "claims literally comprehend numerous polymers in addition to the one specifically described in appellant's specification" because no persuasive reason was given by the Patent Office why the specification does not realistically enable one skilled in the art to practice the invention as broadly as it is claimed. *In re Bowen* , 492 F.2d at 863, 181 USPQ at 51-52. The same can be said here. The only impediments are the time and cost of a dose response study, which the district court found could be performed by "those who were expert in the field and actually working with bone, doing electrical stimulation experiments . . . , " i.e., those skilled in the art. Moreover, as

we have noted, Telectronic's device using different electrode materials actually operated within the current parameters disclosed in the specification.

We conclude that the district court erred in its nonenablement conclusion and that facts supported by clear and convincing evidence of invalidity were not adduced.

In view of our decision, we need not consider the district court's denial of attorney fees to Telectronics.

Costs

The parties shall bear their respective costs.

AFFIRMED-IN-PART AND REVERSED-IN-PART

- End of Case -

8 USPQ2d 1400
In re Wands
U.S. Court of Appeals Federal Circuit

No. 87-1454

Decided September 30, 1988

858 F2d 731

Headnotes

PATENTS

[1] Patentability/Validity -- Adequacy of disclosure (▶ 115.12)

Data disclosed in application for immunoassay method patent, which shows that applicants screened nine of 143 cell lines developed for production of antibody necessary to practice invention, stored remainder of said cell lines, and found that four out of nine cell lines screened produced antibody falling within limitation of claims, were erroneously interpreted by Board of Patent Appeals and Interferences as failing to meet disclosure requirements of 35 USC 112, since board's characterization of stored cell lines as "failures" demonstrating unreliability of applicants' methods was improper in view of fact that such unscreened cell lines prove nothing concerning probability of success of person skilled in art attempting to obtain requisite antibodies using applicants' methods.

[2] Patentability/Validity -- Adequacy of disclosure (▶ 115.12)

Disclosure in application for immunoassay method patent does not fail to meet enablement requirement of 35 USC 112 by requiring "undue experimentation," even though production of monoclonal antibodies necessary to practice invention first requires production and screening of numerous antibody producing cells or "hybridomas," since practitioners of art are prepared to screen negative hybridomas in order to find those that produce desired antibodies, since in monoclonal antibody art one "experiment" is not simply screening of one hybridoma but rather is entire attempt to make desired antibody, and since record indicates that amount of effort needed to obtain desired antibodies is not excessive, in view of applicants' success in each attempt to produce antibody that satisfied all claim limitations.

Case History and Disposition

Appeal from decision of Patent and Trademark Office, Board of Patent Appeals and Interferences.

Application for patent of Jack R. Wands, Vincent R. Zurawski, Jr., and Hubert J. P. Schoemaker, serial number 188,735. From decision of Board of Patent Appeals and Interferences affirming rejection of application, applicants appeal. Reversed; Newman, J., concurring in part and dissenting in part in separate opinion.

Attorneys

Jorge A. Goldstein, of Saidman, Sterne, Kessler & Goldstein (Henry N. Wixon, with them on brief), Washington, D.C., for appellant.

John H. Raubitschek, associate solicitor (Joseph F. Nakamura and Fred E. McKelvey, with him on brief), PTO, for appellee.

Judge

Before Smith, Newman, and Bissell, circuit judges.

Opinion Text

Opinion By:

Smith, J.

This appeal is from the decision of the Patent and Trademark Office (PTO) Board of Patent Appeals and Interferences (board) affirming the rejection of all remaining claims in appellant's application for a patent, serial No. 188,735, entitled "Immunoassay Utilizing Monoclonal High Affinity IgM

Page 1401

Antibodies," which was filed September 19, 1980. [1] The rejection under 35 U.S.C. §112, first paragraph, is based on the grounds that appellant's written specification would not enable a person skilled in the art to make the monoclonal antibodies that are needed to practice the claimed invention without undue experimentation. We reverse.

[1] *In re Wands* , Appeal No. 673-76 (Bd. Pat. App. & Int. Dec. 30, 1986).

I. *Issue*

The only issue on appeal is whether the board erred, as a matter of law, by sustaining the examiner's rejection for lack of enablement under 35 U.S.C. §112, first paragraph, of all remaining claims in appellants' patent application, serial No. 188,735.

II. *Background*

A. *The Art* .

The claimed invention involves immunoassay methods for the detection of hepatitis B surface antigen by using high-affinity monoclonal antibodies of the IgM isotype. *Antibodies* are a class of proteins (immunoglobulins) that help defend the body against invaders such as viruses and bacteria. An antibody has the potential to bind tightly to another molecule, which molecule is called an antigen. The body has the ability to make millions of different antibodies that bind to different antigens. However, it is only after exposure of an antigen that a complicated *immune response* leads to the production of antibodies against that antigen. For example, on the surface of hepatitis B virus particles there is a large protein called *hepatitis B surface antigen* (HBsAg). As its name implies, it is capable of serving as an antigen. During a hepatitis B infection (or when purified HBsAg is injected experimentally), the body begins to make antibodies that bind tightly and specifically to HBsAg. Such antibodies can be used as reagents for sensitive diagnostic tests (*e.g* ., to detect hepatitis B virus in blood and other tissues, a purpose of the claimed invention). A method for detecting or measuring antigens by using antibodies as reagents is called an *immunoassay* .

Normally, many different antibodies are produced against each antigen. One reason for this diversity is that different antibodies are produced that bind to different regions (determinants) of a large antigen molecule such as HBsAg. In addition, different antibodies may be produced that bind to the same determinant. These usually differ in the tightness with which they bind to the determinant. *Affinity* is a quantitative measure of the strength of antibody-antigen binding. Usually an antibody with a higher affinity for an antigen will be more useful for immunological diagnostic tests than one with a lower affinity. Another source of heterogeneity is that there are several immunoglobulin classes or *isotypes* . Immunoglobulin G (IgG) is the most common isotype in serum. Another isotype, immunoglobulin M (IgM), is prominent early in the immune response. IgM molecules are larger than IgG molecules, and have 10 antigen-binding sites instead of the 2 that are present in IgG. Most immunoassay methods use IgG, but the claimed invention uses only IgM antibodies.

For commercial applications there are many disadvantages to using antibodies from serum. Serum contains a complex mixture of antibodies against the antigen of interest within a much larger pool of antibodies directed at other antigens. There are available only in a limited supply that ends when the donor dies. The goal of monoclonal antibody technology is to produce an unlimited supply of a single purified antibody.

The blood cells that make antibodies are *lymphocytes* . Each lymphocyte makes only one kind of antibody. During an immune response, lymphocytes exposed to their particular antigen divide and

mature. Each produces a *clone* of identical daughter cells, all of which secrete the same antibody. Clones of lymphocytes, all derived from a single lymphocyte, could provide a source of a single homogeneous antibody. However, lymphocytes do not survive for long outside of the body in cell culture.

Hybridoma technology provides a way to obtain large numbers of cells that all produce the same antibody. This method takes advantage of the properties of *myeloma* cells derived from a tumor of the immune system. The cancerous myeloma cells can divide indefinitely in vitro. They also have the potential ability to secrete antibodies. By appropriate experimental manipulations, a myeloma cell can be made to fuse with a lymphocyte to produce a single hybrid cell (hence, a hybridoma) that contains the genetic material of both cells. The hybridoma secretes the same antibody that was made by its parent lymphocyte, but acquires the capability of the myeloma cell to divide and grow indefinitely in cell culture. Antibodies produced by a clone of hybridoma cells (i.e., by hybridoma

Page 1402

cells that are all progeny of a single cell) are called monoclonal antibodies. [2]

---

[2] For a concise description of monoclonal antibodies and their use in immunoassay see *Hybritech, Inc. v. Monoclonal Antibodies, Inc* ., 802 F.2d 1367, 1368-71, 231 USPQ 81, 82-83 (Fed.Cir. 1986), cert. denied , 107 S.Ct. 1606 (1987).

B. *The Claimed Invention* .

The claimed invention involves methods for the immunoassay of HBsAg by using high-affinity monoclonal IgM antibodies. Jack R. Wands and Vincent R. Zurawski, Jr., two of the three coinventors of the present application, disclosed methods for producing monoclonal antibodies against HBsAg in United States patent No. 4,271,145 (the '145 patent), entitled "Process for Producing Antibodies to Hepatitis Virus and Cell Lines Therefor," which patent issued on June 2, 1981. The '145 patent is incorporated by reference into the application on appeal. The specification of the '145 patent teaches a procedure for immunizing mice against HBsAg, and the use of lymphocytes from these mice to produce hybridomas that secrete monoclonal antibodies specific for HBsAg. The '145 patent discloses that this procedure yields both IgG and IgM antibodies with high-affinity binding to HBsAg. For the stated purpose of complying with the best mode requirement of 35 U.S.C. §112, first paragraph, a hybridoma cell line that secretes IgM antibodies against HBsAg (the 1F8 cell line) was deposited at the American Type Culture Collection, a recognized cell depository, and became available to the public when the '145 patent issued.

The application on appeal claims methods for immunoassay of HBsAg using monoclonal antibodies such as those described in the '145 patent. Most immunoassay methods have used monoclonal antibodies of the IgG isotype. IgM antibodies were disfavored in the prior art because of their sensitivity to reducing agents and their tendency to self-aggregate and precipitate. Appellants found that their monoclonal IgM antibodies could be used for immunoassay of HbsAg with unexpectedly high sensitivity and specificity. Claims 1, 3, 7, 8, 14, and 15 are drawn to methods for the immunoassay of HBsAg using high-affinity IgM monoclonal antibodies. Claims 19 and 25-27 are for chemically *modified* (*e.g* ., radioactively labeled) monoclonal IgM antibodies used in the assays. The broadest method claim reads:

> 1. An immunoassay method utilizing an antibody to assay for a substance comprising hepatitis B-surface antigen (HBsAg) determinants which comprises the steps of:
>
> contacting a test sample containing said substance comprising HBsAg determinants with said antibody; and
>
> determining the presence of said substance in said sample;
>
> wherein said antibody is a monoclonal high affinity IgM antibody having a binding affinity constant for said HBsAg determinants of at least $10^{9}M^{-1}$.

Certain claims were rejected under 35 U.S.C. §103; these rejections have not been appealed. Remaining claims 1, 3, 7, 8, 14, 15, 19, and 25-27 were rejected under 35 U.S.C. §112, first paragraph, on the grounds that the disclosure would not enable a person skilled in the art to make and use the invention without undue experimentation. The rejection is directed solely to whether the specification enables one skilled in the art to make the monoclonal antibodies that are needed to practice the invention. The position of the PTO is that data presented by Wands show that the

production of high-affinity IgM anti-HBsAg antibodies is unpredictable and unreliable, so that it would require undue experimentation for one skilled in the art to make the antibodies.

III. *Analysis*

A. *Enablement by Deposit of Micro-organisms and Cell Lines .*

The first paragraph of 35 U.S.C. §112 requires that the specification of a patent must enable a person skilled in the art to make and use the claimed invention. "Patents * * * are written to enable those skilled in the art to practice the invention." [3] A patent need not disclose what is well known in the art. [4] Although we review underlying facts found by the board under a "clearly erroneous" standard, [5] we review enablement as a question of law. [6]

---

[3] *W.L. Gore & Assocs., Inc. v. Garlock, Inc* ., 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed.Cir. 1983), cert. denied , 469 U.S. 851 (1984).

[4] *Lindemann Maschinenfabrik GMBH v. American Hoist & Derrick Co* ., 730 F.2d 1452, 1463, 221 USPQ 481, 489 (Fed.Cir. 1984).

[5] *Coleman v. Dines* , 754 F.2d 353, 356, 224 USPQ 857, 859 (Fed.Cir. 1985).

[6] *Moleculon Research Corp. v. CBS, Inc* ., 793 F.2d 1261, 1268, 229 USPQ 805, 810 (Fed.Cir. 1986), cert. denied , 107 S.Ct. 875 (1987); *Raytheon Co. v. Roper Corp* ., 724 F.2d 951, 960 n.6, 220 USPQ 592 , 599 n.6 (Fed.Cir. 1983), cert. denied , 469 U.S. 835 [225 USPQ 232] (1984).

Where an invention depends on the use of living materials such as microorganisms or

Page 1403

cultured cells, it may be impossible to enable the public to make the invention (i.e., to obtain these living materials) solely by means of a written disclosure. One means that has been developed for complying with the enablement requirement is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues. [7] Administrative guidelines and judicial decisions have clarified the conditions under which a deposit of organisms can satisfy the requirements of section 112. [8] A deposit has been held necessary for enablement where the starting materials (i.e., the living cells used to practice the invention, or cells from which the required cells can be produced) are not readily available to the public. [9] Even when starting materials are available, a deposit has been necessary where it would require undue experimentation to make the cells of the invention from the starting materials. [10]

---

[7] *In re Argoudelis* , 434 F.2d 1390, 1392-93, 168 USPQ 99, 101-02 (CCPA 1970).

[8] *In re Lundak* , 773 F.2d 1216, 227 USPQ 90 (Fed.Cir. 1985); *Feldman v. Aunstrup* , 517 F.2d 1351, 186 USPQ 108 (CCPA 1975), cert. denied , 424 U.S. 912 [188 USPQ 720] (1976); Manual of Patent Examining Procedure (MPEP) 608.01 (p)(C) (5th ed. 1983, rev. 1987). *See generally* Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement* , 67 J. Pat. Trademark Off. Soc'y 569 (1985).

[9] *In re Jackson* , 217 USPQ 804, 807-08 (Bd. App. 1982) (strains of a newly discovered species of bacteria isolated from nature); *Feldman* , 517 F.2d 1351, 186 USPQ 108 (uncommon fungus isolated from nature); *In re Argoudelis* , 434 F.2d at 1392, 168 USPQ at 102 (novel strain of antibiotic-producing microorganism isolated from nature); *In re Kropp* , 143 USPQ 148, 152 (Bd. App. 1959) (newly discovered microorganism isolated from soil).

[10] *Ex parte Forman* , 230 USPQ 546, 547 (Bd. Pat. App. & Int. 1986) (genetically engineered bacteria where the specification provided insufficient information about the amount of time and effort required); *In re Lundak* , 773 F.2d 1216, 227 USPQ 90 (unique cell line produced from another cell line by mutagenesis).

In addition to satisfying the enablement requirement, deposit of organisms also can be used to establish the filing date of the application as the prima facie date of invention, [11] and to satisfy the requirement under 35 U.S.C. §114 that the PTO be guaranteed access to the invention during pendency of the application. [12] Although a deposit may serve these purposes, we recognized, in *In re Lundak* , [13] that these purposes, nevertheless, may be met in ways other than by making a deposit.

---

[11] *In re Lundak* , 773 F.2d at 1222, 227 USPQ at 95-96; *In re Feldman* , 517 F.2d at 1355, 186 USPQ at 113; *In re Argoudelis* , 434 F.2d at 1394-96, 168 USPQ at 103-04 (Baldwin, J. concurring).

[12] *In re Lundak* , 773 F.2d at 1222, 227 USPQ at 95-96; *In re Feldman* , 517 F.2d at 1354, 186 USPQ at 112.

[13] *In re Lundak* , 773 F.2d at 1222, 227 USPQ at 95-96.

A deposit also may satisfy the best mode requirement of section 112, first paragraph, and it is for this reason that the 1F8 hybridoma was deposited in connection with the '145 patent and the current application. Wands does not challenge the statements by the examiner to the effect that, although the deposited 1F8 line enables the public to perform immunoassays with antibodies produced by that single hybridoma, the deposit does not enable the generic claims that are on appeal. The examiner rejected the claims on the grounds that the written disclosure was not enabling and that the deposit was inadequate. Since we hold that the written disclosure fully enables the claimed invention, we need not reach the question of the adequacy of deposits.

B. *Undue Experimentation* .

Although inventions involving microorganisms or other living cells often can be enabled by a deposit, [14] a deposit is not always necessary to satisfy the enablement requirement. [15] No deposit is necessary if the biological organisms can be obtained from readily available sources or derived from readily available starting materials through routine screening that does not require undue experimentation. [16] Whether the specification in an application involving living cells (here, hybridomas) is enabled without a deposit must be decided on the facts of the particular case. [17]

[14] *In re Argoudelis* , 434 F.2d at 1393, 168 USPQ at 102.

[15] *Tabuchi v. Nubel* , 559 F.2d 1183, 194 USPQ 521 (CCPA 1977).

[16] *Id* . at 1186-87, 194 USPQ at 525; *Merck & Co. v. Chase Chem. Co* ., 273 F.Supp. 68, 77, 155 USPQ 139, 146 (D.N.J. 1967); *Guaranty Trust Co. v. Union Solvents Corp* ., 54 F.2d 400, 403-06, 12 USPQ 47, 50-53 (D. Del. 1931), *aff'd* , 61 F.2d 1041, 15 USPQ 237 (3d Cir. 1932), *cert. denied* , 288 U.S. 614 (1933); MPEP 608.01 (p)(C) ("No problem exists when the microorganisms used are known and readily available to the public.").

[17] *In re Jackson* , 217 USPQ at 807; *see In re Metcalfe* , 410 F.2d 1378, 1382, 161 USPQ 789, 792 (CCPA 1969).

Appellants contend that their written specification fully enables the practice of

Page 1404

their claimed invention because the monoclonal antibodies needed to perform the immunoassays can be made from readily available starting materials using methods that are well known in the monoclonal antibody art. Wands states that application of these methods to make high-affinity IgM anti-HBsAg antibodies requires only routine screening, and that does not amount to undue experimentation. There is no challenge to their contention that the starting materials (i.e., mice, HBsAg antigen, and myeloma cells) are available to the public. The PTO concedes that the methods used to prepare hybridomas and to screen them for high-affinity IgM antibodies against HBsAg were either well known in the monoclonal antibody art or adequately disclosed in the '145 patent and in the current application. This is consistent with this court's recognition with respect to another patent application that methods for obtaining and screening monoclonal antibodies were well known in 1980. [18] The sole issue is whether, in this particular case, it would require undue experimentation to produce high-affinity IgM monoclonal antibodies.

[18] *Hybritech* , 802 F.2d at 1384, 231 USPQ at 94.

Enablement is not precluded by the necessity for some experimentation such as routine screening. [19] However, experimentation needed to practice the invention must not be undue experimentation. [20] "the key word is 'undue,' not 'experimentation.' " [21]

[19] *Id.; Atlas Powder Co. v. E.I. DuPont De Nemours & Co* ., 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed.Cir. 1984); *In re Angstadt* , 537 F.2d at 502-504, 190 USPQ at 218; *In re Geerdes* , 491 F.2d 1260, 1265, 180 USPQ 789, 793 (CCPA 1974); *Mineral Separation, Ltd. v. Hyde* , 242 U.S. 261, 270-71 (1916).

[20] *Hybritech* , 802 F.2d at 1384, 231 USPQ at 94; *W.L. Gore* , 721 F.2d at 1557, 220 USPQ at 316; *In re Colianni* , 561 F.2d 220, 224, 195 USPQ 150, 153 (CCPA 1977) (Miller, J., concurring).

[21] *In re Angstadt* , 537 F.2d at 504, 190 USPQ at 219.

> The determination of what constitutes undue experimentation in a given case requires the application of a standard of reasonableness, having due regard for the nature of the invention and the state of the art. *Ansul Co. v. Uniroyal, Inc.* [448 F.2d 872, 878-79; 169 USPQ 759, 762-63 (2d Cir. 1971), cert. denied , 404 U.S. 1018 [172 USPQ 257] (1972)]. The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed * * * . [22]

[22] *In re Jackson* , 217 USPQ at 807.

The term "undue experimentation" does not appear in the statute, but it is well established that enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. [23] Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations. The board concluded that undue experimentation would be needed to practice the invention on the basis of experimental data presented by Wands. These data are not in dispute. However, Wands and the board disagree strongly on the conclusion that should be drawn from that data.

[23] *See Hybritech* , 802 F.2d at 1384, 231 USPQ at 94; *Atlas Powder* , 750 F.2d at 1576, 224 USPQ at 413.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in *Ex parte Forman* . [24] They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. [25]

[24] *Ex parte Forman* , 230 USPQ at 547.

[25] *Id.; see In re Colianni* , 561 F.2d at 224, 195 USPQ at 153 (Miller, J., concurring); *In re Rainer* , 347 F.2d 574, 577, 146 USPQ 218, 221 (CCPA 1965).

In order to understand whether the rejection was proper, it is necessary to discuss further the methods for making specific monoclonal antibodies. The first step for making monoclonal antibodies is to immunize an animal. The '145 patent provides a detailed description of procedures for immunizing a specific strain of mice against HBsAg. Next the spleen, an organ rich in lymphocytes, is removed and the lymphocytes are separated from the other spleen cells. The lymphocytes are mixed with myeloma cells, and the mixture is treated to cause a few of the cells to fuse with each other. Hybridoma cells that secrete the desired antibodies then must be isolated from the enormous number of other cells in the mixture. This is done through a series of screening procedures.

The first step is to separate the hybridoma cells from unfused lymphocytes and myeloma cells. The cells are cultured in a medi

Page 1405

um in which all the lymphocytes and myeloma cells die, and only the hybridoma cells survive. The next step is to isolate and clone hybridomas that make antibodies that bind to the antigen of interest. Single hybridoma cells are placed in separate chambers and are allowed to grow and divide. After there are enough cells in the clone to produce sufficient quantities of antibody to analyze, the antibody is assayed to determine whether it binds to the antigen. Generally, antibodies from many clones do

not bind the antigen, and these clones are discarded. However, by screening enough clones (often hundreds at a time), hybridomas may be found that secrete antibodies against the antigen of interest.

Wands used a commercially available radioimmunoassay kit to screen clones for cells that produce antibodies directed against HBsAg. In this assay the amount of radioactivity bound gives some indication of the strength of the antibody-antigen binding, but does not yield a numerical affinity constant, which must be measured using the more laborious Scatchard analysis. In order to determine which anti-HBsAg antibodies satisfy all of the limitations of appellants' claims, the antibodies require further screening to select those which have an IgM isotype and have a binding affinity constant of at least $10^{9}M^{-1}$. [26] The PTO does not question that the screening techniques used by Wands were well known in the monoclonal antibody art.

[26] The examiner, the board, and Wands all point out that, technically, the strength of antibody-HBsAg binding is measured as *avidity* , which takes into account multiple determinants on the HBsAg molecule, rather than affinity. Nevertheless, despite this correction, all parties then continued to use the term "affinity." We will use the terminology of the parties. Following the usage of the parties, we will also use the term "high-affinity" as essentially synonymous with "having a binding affinity constant of at least $10^{9}M^{-1}$."

During prosecution Wands submitted a declaration under 37 C.F.R §1.132 providing information about all of the hybridomas that appellants had produced before filing the patent application. The first four fusions were unsuccessful and produced no hybridomas. The next six fusion experiments all produced hybridomas that made antibodies specific for HBsAg. Antibodies that bound at least 10,000 cpm in the commercial radioimmunoassay were classified as "high binders." Using this criterion, 143 high-binding hybridomas were obtained. In the declaration, Wands stated that [27]

[27] A table in the declaration presented the binding data for antibodies from every cell line. Values ranged from 13,867 to 125,204 cpm, and a substantial proportion of the antibodies showed binding greater than 50,000 cpm. In confirmation of Dr. Wand's statement, two antibodies with binding less than 25,000 cpm were found to have affinity constants greater than $10^{9}M^{-1}$.

> It is generally accepted in the art that, among those antibodies which are binders with 50,000 cpm or higher, there is a very high likelihood that high affinity (Ka [greater than] $10^{9}M^{-1}$) antibodies will be found. However, high affinity antibodies can also be found among high binders of between 10,000 and 50,000, as is clearly demonstrated in the Table.

The PTO has not challenged this statement.

The declaration stated that a few of the high-binding monoclonal antibodies from two fusions were chosen for further screening. The remainder of the antibodies and the hybridomas that produced them were saved by freezing. Only nine antibodies were subjected to further analysis. Four (three from one fusion and one from another fusion) fell within the claims, that is, were IgM antibodies and had a binding affinity constant of at least $10^{9}M^{-1}$. Of the remaining five antibodies, three were found to be IgG, while the other two were IgM for which the affinity constants were not measured (although both showed binding well above 50,000 cpm).

Apparently none of the frozen cell lines received any further analysis. The declaration explains that after useful high-affinity IgM monoclonal antibodies to HBsAg had been found, it was considered unnecessary to return to the stored antibodies to screen for more IgMs. Wands says that the existence of the stored hybridomas was disclosed to the PTO to comply with the requirement under 37 C.F.R. §1.56 that applicants fully disclose all of their relevant data, and not just favorable results. [28] How these stored hybridomas are viewed is central to the positions of the parties.

[28] *See Rohm & Haas Co. v. Crystal Chem. Co* ., 722 F.2d 1556, 220 USPQ 98 (Fed.Cir. 1983).

The position of the board emphasizes the fact that since the stored cell lines were not completely tested, there is no proof that any of them are IgM antibodies with a binding affinity constant of at least $10^{9}M^{-1}$. Thus, only 4 out of 143 hybridomas, or 2.8 percent, were *proved* to fall within the claims. Furthermore, antibodies that were proved to be high-affinity IgM came from only 2 of 10 fusion experiments. These statistics are viewed by the board as evidence that appellants' methods

were not predictable or reproducible. The board concludes that Wands' low rate of demonstrated success shows that a person skilled in the art would have to

Page 1406

engage in undue experimentation in order to make antibodies that fall within the claims.

Wands views the data quite differently. Only nine hybridomas were actually analyzed beyond the initial screening for HBsAg binding. Of these, four produced antibodies that fell within the claims, a respectable 44 percent rate of success. (Furthermore, since the two additional IgM antibodies for which the affinity constants were never measured showed binding in excess of 50,000 cpm, it is likely that these also fall within the claims.) Wands argues that the remaining 134 unanalyzed, stored cell lines should not be written off as failures. Instead, if anything, they represent partial success. Each of the stored hybridomas had been shown to produce a high-binding antibody specific for HBsAg. Many of these antibodies showed binding above 50,000 cpm and are thus highly likely to have a binding affinity constant of at least $10^{9}M^{-1}$. Extrapolating from the nine hybridomas that were screened for isotype (and from what is well known in the monoclonal antibody art about isotype frequency), it is reasonable to assume that the stored cells include some that produce IgM. Thus, if the 134 incompletely analyzed cell lines are considered at all, they provide some support (albeit without rigorous proof) to the view that hybridomas falling within the claims are not so rare that undue experimentation would be needed to make them.

The first four fusion attempts were failures, while high-binding antibodies were produced in the next six fusions. Appellants contend that the initial failures occurred because they had not yet learned to fuse cells successfully. Once they became skilled in the art, they invariably obtained numerous hybridomas that made high-binding antibodies against HBsAg and, in each fusion where they determined isotype and binding affinity they obtained hybridomas that fell within the claims.

Wands also submitted a second declaration under 37 C.F.R. §1.132 stating that after the patent application was submitted they performed an eleventh fusion experiment and obtained another hybridoma that made a high-affinity IgM anti-HBsAg antibody. No information was provided about the number of clones screened in that experiment. The board determined that, because there was no indication as to the number of hybridomas screened, this declaration had very little value. While we agree that it would have been preferable if Wands had included this information, the declaration does show that when appellants repeated their procedures they again obtained a hybridoma that produced an antibody that fit all of the limitations of their claims.

[1] We conclude that the board's interpretation of the data is erroneous. It is strained and unduly harsh to classify the stored cell lines (each of which was proved to make high-binding antibodies against HBsAg) as failures demonstrating that Wands' methods are unpredictable or unreliable. [29] At worst, they prove nothing at all about the probability of success, and merely show that appellants were prudent in not discarding cells that might someday prove useful. At best, they show that high-binding antibodies, the starting materials for IgM screening and Scatchard analysis, can be produced in large numbers. The PTO's position leads to the absurd conclusion that the more hybridomas an applicant makes and saves without testing the less predictable the applicant's results become. Furthermore, Wands' explanation that the first four attempts at cell fusion failed only because they had not yet learned to perform fusions properly is reasonable in view of the fact that the next six fusions were all successful. The record indicates that cell fusion is a technique that is well known to those of ordinary skill in the monoclonal antibody art, and there has been no claim that the fusion step should be more difficult or unreliable where the antigen is HBsAg than it would be for other antigens.

---

[29] Even if we were to accept the PTO's 2.8% success rate, we would not be required to reach a conclusion of undue experimentation. Such a determination must be made in view of the circumstances of each case and cannot be made solely by reference to a particular numerical cutoff.

---

[2] When Wands' data is interpreted in a reasonable manner, analysis considering the factors enumerated in *Ex parte Forman* leads to the conclusion that undue experimentation would not be required to practice the invention. Wands' disclosure provides considerable direction and guidance on how to practice their invention and presents working examples. There was a high level of skill in the art at the time when the application was filed, and all of the methods needed to practice the invention were well known.

The nature of monoclonal antibody technology is that it involves screening hybridomas to determine which ones secrete antibody with desired characteristics. Practitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody. No evidence was presented by either party on how many hybridomas would be viewed by those in the art as requiring undue experimentation to screen. However, it seems unlikely that un

Page 1407

due experimentation would be defined in terms of the number of hybridomas that were never screened. Furthermore, in the monoclonal antibody art it appears that an "experiment" is not simply the screening of a single hybridoma, but is rather the entire attempt to make a monoclonal antibody against a particular antigen. This process entails immunizing animals, fusing lymphocytes from the immunized animals with myeloma cells to make hybridomas, cloning the hybridomas, and screening the antibodies produced by the hybridomas for the desired characteristics. Wands carried out this entire procedure three times, and was successful each time in making at least one antibody that satisfied all of the claim limitations. Reasonably interpreted, Wands' record indicates that, in the production of high-affinity IgM antibodies against HBsAG, the amount of effort needed to obtain such antibodies is not excessive. Wands' evidence thus effectively rebuts the examiner's challenge to the enablement of their disclosure. [30]

[30] *In re Strahilevitz* , 668 F.2d 1229, 1232, 212 USPQ 561, 563 (CCPA 1982).

IV. *Conclusion*

Considering all of the factors, we conclude that it would not require undue experimentation to obtain antibodies needed to practice the claimed invention. Accordingly, the rejection of Wands' claims for lack of enablement under 35 U.S.C. §112, first paragraph, is *reversed*.

REVERSED

Concurring/Dissenting Opinion Text

Concurrence/Dissent By:

Newman, J., concurring in part, dissenting in part.

A

I concur in the court's holding that additional samples of hybridoma cell lines that produce these high-affinity IgM monoclonal antibodies need not be deposited. This invention, as described by Wands, is not a selection of a few rare cells from many possible cells. To the contrary, Wands states that all monoclonally produced IgM antibodies to hepatitis B surface antigen have the desired high avidity and other favorable properties, and that all are readily preparable by now-standard techniques.

Wands states that his United States Patent No. 4,271,145 describes fully operable techniques, and is distinguished from his first four failed experiments that are referred to in the Rule 132 affidavit. Wands argues that these biotechnological mechanisms are relatively well understood and that the preparations can be routinely duplicated by those of skill in this art, as in *Hybritech, Inc. v. Monoclonal Antibodies, Inc* ., 802 F.2d 1367, 1380, 231 USPQ 81, 94 (Fed.Cir. 1986), cert. denied , 107 S.Ct. 1606 (1987). I agree that it is not necessary that there be a deposit of multiple exemplars of a cell system that is readily reproduced by known, specifically identified techniques.

B

I would affirm the board's holding that Wands has not complied with 35 U.S.C. §112, first paragraph, in that he has not provided data sufficient to support the breadth of his generic claims. Wands' claims on appeal include the following:

> 19. Monoclonal high affinity IgM antibodies immunoreactive with HBsAg determinants, wherein said antibodies are coupled to an insoluble solid phase, and wherein the binding affinity constant of said antibodies for said HBsAg determinants is at least $10^{9}M^{-1}$.
>
> 26. Monoclonal high affinity IgM antibodies immunoreactive with hepatitis B surface antigen.

Wands states that he obtained 143 "high binding monoclonal antibodies of the right specificity" in the successful fusions; although he does not state how they were determined to be high binding or of the right specificity, for Wands also states that only nine of these 143 were tested.

Of these nine, four (three from one fusion and one from another fusion) were found to have the claimed high affinity and to be of the IgM isotype. Wands states that the other five were either of a different isotype or their affinities were not determined. (This latter statement also appears to contradict his statement that all 143 were "high binding".)

Wands argues that a "success rate of four out of nine", or 44.4%, is sufficient to support claims to the entire class. The Commissioner deems the success rate to be four out of 143, or 2.8%; to which Wands responds with statistical analysis as to how unlikely it is that Wands selected the only four out of 143 that worked. Wands did not, however, prove the right point. The question is whether Wands, by testing nine out of 143 (the Commissioner points out that the randomness of the sample was not established), and finding that four out of the nine had the desired properties, has provided sufficient experimental support for the breadth of the requested claims, in the context that "experi

Page 1408

ments in genetic engineering produce, at best, unpredictable results", quoting from *Ex parte Forman* , 230 USPQ 546, 547 (Bd.Pat.App. and Int. 1986).

The premise of the patent system is that an inventor, having taught the world something it didn't know, is encouraged to make the product available for public and commercial benefit, by governmental grant of the right to exclude others from practice of that which the inventor has disclosed. The boundary defining the excludable subject matter must be carefully set: it must protect the inventor, so that commercial development is encouraged; but the claims must be commensurate with the inventor's contribution. Thus the specification and claims must meet the requirements of 35 U.S.C. §112. *In re Fisher* , 427 F.2d 833, 839, 166 USPQ 18, 23-24 (CCPA 1970).

As the science of biotechnology matures the need for special accommodation, such as the deposit of cell lines or microorganisms, may diminish; but there remains the body of law and practice on the need for sufficient disclosure, including experimental data when appropriate, that reasonably support the scope of the requested claims. That law relates to the sufficiency of the description of the claimed invention, and if not satisfied by deposit, must independently meet the requirements of Section 112.

Wands is not claiming a particular, specified IgM antibody. He is claiming all such monoclonal antibodies in assay for hepatitis B surface antigen, based on his teaching that such antibodies have uniformly reproducible high avidity, free of the known disadvantages of IgM antibodies such as tendency to precipitate or aggregate. It is incumbent upon Wands to provide reasonable support for the proposed breadth of his claims. I agree with the Commissioner that four exemplars shown to have the desired properties, out of the 143, do not provide adequate support.

Wands argues that the law should not be "harsher" where routine experiments take a long time. However, what Wands is requesting is that the law be less harsh. As illustrated in extensive precedent on the question of how much experimentation is "undue", each case must be determined on its own facts. *See , e.g., W.L. Gore & Assocs., Inc. v. Garlock, Inc* ., 721 F.2d 1540, 1557, 220 USPQ 303, 316 (Fed.Cir. 1983), cert. denied , 469 U.S. 851 (1984); *In re Angstadt* , 537 F.2d 498, 504, 190 USPQ 214, 218 (CCPA 1976); *In re Cook* , 439 F.2d 730, 734-35, 169 USPQ 298, 302-03 (CCPA 1971).

The various criteria to be considered in determining whether undue experimentation is required are discussed in, for example, *Fields v. Conover* , 443 F.2d 1386, 170 USPQ 276 (CCPA 1971); *In re Rainer* , 347 F.2d 574, 146 USPQ 218 (CCPA 1965); *Ex parte Forman* , 230 USPQ at 547. Wands must provide sufficient data or authority to show that his results are reasonably predictable within the scope of the claimed generic invention, based on experiment and/or scientific theory. In my view he has not met this burden.

- End of Case -

ISSN 1526-8535

Source: USPQ, 1st Series (1929 - 1986) > U.S. Court of Appeals, Federal Circuit > Hybritech Incorporated v. I Antibodies, Inc., 231 USPQ 81 (Fed. Cir. 1986)

231 USPQ 81
Hybritech Incorporated v. Monoclonal Antibodies, Inc.
U.S. Court of Appeals Federal Circuit

No. 86-531

Decided September 19, 1986

802 F2d 1367

Headnotes

PATENTS

[1] Patentability -- In general (▶ 51.01)

Federal district court's finding that evidence was lacking as to when, before May 1980, claimed invention of using monoclonal antibodies in "sandwich" assays was conceived by patent holder, is clearly erroneous, in view of evidence demonstrating patent holder's earlier efforts in developing claimed invention by using prior art technology to produce necessary monoclonal antibodies in diagnostic sandwich assay kits, in view of evidence demonstrating that exploiting monoclonal antibodies for use in sandwich assays was one of patent holder's major objectives, and in view of laboratory notebooks and research program that fully corroborate testimonial evidence of conception, since such evidence clearly supports holding that patent holder conceived claimed invention before patent challenger and that patent challenger's work is not prior art.

[2] Patentability -- Anticipation -- In general (▶ 51.201)

Prior art work that involved "sandwich" assay to extent that antigen was sandwiched between two monoclonal antibodies, but that did not involve detecting presence of or quantitating antigen, did not anticipate claimed invention, since it did not meet its every element.

[3] Patentability -- Invention -- In general (▶ 51.501)

Articles which "predicted" widespread use of monoclonal antibodies but which are dated well after patented monoclonal assay's date of conception and within one year of its filing date, are not prior art, nor should earlier articles which discussed production of monoclonal antibodies, although clearly prior art, have been relied upon to establish obviousness of trying monoclonal antibodies of particular affinity in "sandwich" immunoassay that detects presence of or quantitates antigen, since such articles do not suggest how that end may be accomplished, and since "obvious to try" is improper consideration in adjudicating obviousness issue.

[4] Patentability -- Evidence of -- Commercial success -- Causes (▶ 51.4555)

Trial court's finding that "sudden availability" of monoclonals was reason for commercial success of patented diagnostic kits is clearly erroneous, in view of evidence demonstrating that at least three years passed between time monoclonal antibodies were available in adequate supply and time patent holder began selling its kits.

[5] Claims -- Indefinite -- Chemical (▶ 20.553)

Federal district court erred in holding that claims for monoclonal assay are indefinite because antibody affinity cannot be estimated with any consistency, since calculating affinity was known in art at time of filing, and since such claims reasonably apprise those skilled in art and are as precise as subject matter permits, even though calculations are not precise or "standard."

Particular Patents

Particular patents -- Assays

4,376,110, David and Green, Immunometric Assays Using Monoclonal Antibodies, holding of invalidity *reversed*.

Case History and Disposition

Page 81

Appeal from District Court for the Northern District of California, Conti, J.; 227 USPQ 215 .

Action by Hybritech Incorporated, against Monoclonal Antibodies, Inc., for patent infringement. From judgment for defendant, plaintiff appeals. Reversed and *remanded*.

Attorneys

Douglas E. Olson, and Lyon & Lyon, both of Los Angeles, Calif. (James W. Geriak and Bradford J. Duft, both of Los Angeles, Calif., on the brief) for appellant.

David J. Brezner, and Flehr, Hohback, Test, Albritton & Herbert, both of San Francisco, Calif. (Barry E. Britschneider and Herbert I. Cantor, both of Washington, D.C., of counsel) for appellee.

Judge

Before Rich, Davis, and Smith, Circuit Judges.

Opinion Text

Opinion By:

Rich, Circuit Judge.

This appeal is from the August 28, 1985, decision of the United States District Court for the Northern District of California, 623 F.Supp. 1344, 227 USPQ 215 , in favor of defendant Monoclonal Antibodies, Inc. (Monoclonal) holding that all 29 claims of plaintiff's patent No. 4,376,110 entitled "Immunometric Assays Using Monoclonal Antibodies" ('110 patent), issued to Dr. Gary S. David and Howard E. Greene and assigned to Hybritech Incorporated (Hybritech), are invalid as anticipated under 35 USC 102(g), for obvious

Page 82

ness under §103, and under §112 first and second paragraphs. We reverse and remand.

Background

Vetebrates defend themselves against invasion by microorganisms by producing antibodies, proteins which can complex with the invading microorganisms and target them for destruction or removal. In fact, any foreign molecule of sufficient size can act as a stimulus for antibody production. Such foreign molecules, or antigens, bear particular sites or epitopes that represent antibody recognition sites. B cell lymphocytes, the cells that actually produce antibodies, recognize and respond to an epitope on an antigen by reproducing or cloning themselves and then producing antibodies specific to that epitope. Even if the antigen is highly purified, the lymphocytes will produce antibodies specific to different epitopes on the antigen and so produce antibodies with different specificities. Furthermore, because the body is exposed to many different antigens, the blood of a vertebrate will contain antibodies to many different antigenic substances.

Scientists and clinicians have long employed the ability of antibodies to recognize and complex with antigens as a tool to identify or label particular cells or molecules and to separate them from a mixture. Their source of antibodies has been primarily the serum separated from the blood of a vertebrate immunized or exposed to the antigen. Serum, however, contains a mixture of antibodies directed to numerous antigens and to any number of epitopes on a particular antigen. Because such a mixture of antibodies arises from many different clones of lymphocytes, it is called "polyclonal."

Recent technological advances have made it possible to isolate and cultivate a single clone of lymphocytes to obtain a virtually unlimited supply of antibodies specific to one particular epitope. These antibodies, known as "monoclonal antibodies" because they arise from a single clone of lymphocytes, are produced by a relatively new technology known as the hybridoma. Hybridomas are produced by fusing a particular cancer cell, the myeloma cell, with spleen cells from a mouse that has been injected or immunized with the antigen. These fusions are isolated by transferring them to a growth fluid that kills off the unfused cancer cells, the unfused spleen cells dying off by themselves. The fused hybrid spleen and myeloma cells, called hybridomas, produce antibodies to the antigen initially injected into the mouse. The growth fluid containing the hybridomas is then diluted and put into individual test tubes or wells so that there is only one hybridoma per tube or well. Each hybridoma then reproduces itself and these identical hybridomas each produce identical monoclonal antibodies having the same affinity and specificity. In this way, a virtually unlimited supply of identical antibodies is created, directed to only one epitope on an antigen rather than, as with polyclonal antibodies, to many different epitopes on many different antigens.

In addition to the specificity of antibodies to particular epitopes discussed above, antibodies also have a characteristic "sensitivity," the ability to detect and react to antigens. Sensitivity is expressed in terms of "affinity:" the greater an antibody's ability to bind with a particular antigen, the greater the antibody's affinity. The strength of that antibody-antigen bond is in part dependent upon the antibody's "affinity constant," expressed in liters per mole, for the antigen.

Immunoassays, the subject matter of the '110 patent are diagnostic methods for determining the presence or amount of antigen in body fluids such as blood or urine by employing the ability of an antibody to recognize and bind to an antigen. Generally, the extent to which the antibody binds to the antigen to be quantitated is an indication of the amount of antigen present in the fluid. Labelling the antibody or, in some cases, the antigen, with either a radioactive substance, I 125, or an enzyme makes possible the detection of the antibody-antigen complex. In an extreme case, where the fluid sample contains a very low level of the antigen, binding might not occur unless the antibodies selected or "screened" for the procedure are highly sensitive.

In the case of a "competitive" immunoassay, a labelled antigen reagent is bound to a limited and known quantity of antibody reagent. After that reaction reaches equilibrium, the antigen to be detected is added to the mixture and competes with the labelled antigen for the limited number of antibody binding sites. The amount of labelled antigen reagent displaced, if any, in this second reaction indicates the quantity of the antigen to be detected present in the fluid sample. All of the antigen attached to the antibody will be labelled antigen if there is no antigen in the test fluid sample. The advantage of this method is that only a small amount of antibody is needed, its drawback, generally, that the system must reach equilibrium, and thus produces results slowly.

In the case of a "sandwich" assay, otherwise known as an immunometric assay, the latter being a term coined by Dr. Lawton Miles in 1971, a quantity of unlabelled antibody reagent is bound to a solid support surface such as the inside wall of a test tube containing a complex of the fluid sample containing the

Page 83

antigen to be detected and a labelled *antibody* reagent. The result is an insoluble three part complex referred to as a sandwich having antibody bread and antigen filling. This figure is illustrative of the sandwich concept:

Tabular, graphic, or textual material set at this point is not available. Please consult hard copy or call BNA at 1-800-372-1033.

The advantage of the sandwich assay is that it is fast and simple, its drawback that enormous quantities of antibodies are needed.

Hybritech

Hybritech, started in 1978 and joined thereafter by coinventors Green and Dr. David, has, since 1979, been in the business of developing diagnostic kits employing monoclonal antibodies that detect numerous antigens and thus a broad range of conditions such as pregnancy, cancer, growth hormone deficiency, or hepatitis. Examples of antigens include influenza viruses, immunoglobulin E (IgE) which indicates allergic reaction, human chorionic gonadotropin (HCG) which indicates pregnancy, and prostatic acid phosphatase (PAP) which indicates prostate cancer, to name a few. Dr. Adams, a

business-experienced scientist, joined the company in May 1980 as head of research and development. The '110 patent, application for which was filed August 4, 1980, issued March 8, 1983, with claims defining a variety of sandwich assays using monoclonal antibodies. Claim 19, apparently the broadest of the twenty-nine in the patent, is directed generally to a sandwich assay and reads (emphasis ours):

> 19. In *an immunometric assay* to determine the presence or concentration of an antigenic substance in a sample of a fluid comprising forming a ternary complex of a first labelled antibody, said antigenic substance, and a second antibody said second antibody being bound to a solid carrier insoluble in said fluid wherein the presence of the antigenic substance in the samples is determined by measuring either the amount of labelled antibody bound to the solid carrier or the amount of unreacted labelled antibody, *the improvement comprising* employing monoclonal antibodies having an affinity for the antigenic substance of at least about 10 8liters/mole for each of said labelled antibody and said antibody bound to a solid carrier.

Claim 1, directed particularly to a reverse sandwich assay, explained infra, reads:

> 1. A process for the determination of the presence of [sic, or] concentration of an antigenic substance in a fluid comprising the steps:
>
> (a) contacting a sample of the fluid with a measured amount of a soluble first monoclonal antibody to the antigenic substance in order to form a soluble complex of the antibody and antigenic substance present in said sample, said first monoclonal antibody being labelled;
>
> (b) contacting the soluble complex with a second monoclonal antibody to the antigenic substance, said second monoclonal antibody being bound to a solid carrier, said solid carrier being insoluble in said fluid, in order to form an insoluble complex of said first monoclonal antibody, said antigenic substance and said second monoclonal antibody bound to said solid carrier;
>
> (c) separating said solid carrier from the fluid sample and unreacted labelled antibody;
>
> (d) measuring either the amount of labelled antibody; associated with the solid carrier or the amount of unreacted labelled antibody; and
>
> (e) relating the amount of labelled antibody measured with the amount of labelled antibody measured for a control sample prepared in accordance with steps (a)-(d), said control sample being known to be free of said anti-genic substance, to determine the presence of antigenic substance in said fluid sample, or relating the amount of labelled antibody measured with the amount of labelled antibody measured for samples containing known amounts of antigenic substance prepared in accordance with steps (a)-(d) to determine the concentration of antigenic substance in said fluid sample, the first and second monoclonal antibodies having an affinity for the antigenic substance of at least about 10 8liters/mole.

The District Court Decision

Hybritech sued Monoclonal March 2, 1984, for damages and an injunction alleging that the manufacture and sale of Monoclonal's diagnostic kits infringed the '110 patent. Trial without a jury began on August 5, 1985, and concluded August 23, 1985, thirty witnesses having been heard and over 2,000 pages of transcript generated. The district court produced the reported opinion, findings, and con

Page 84

clusions, which use nearly verbatim Monoclonal's *pre-trial* brief and *pre-trial proposed* findings of fact and conclusions of law, in three days, in support of the judgment now on appeal.

The district court held that the claimed subject matter of the '110 patent was neither conceived nor actually reduced to practice before May 1980, and was anticipated under §102(g) by the actual reduction to practice of the invention by Drs. Uotila and Ruoslahti at the La Jolla Cancer Research Foundation (LJCRF) as early as November of 1979 and by the actual reduction to practice of the invention by Drs. Oi and Herzenberg (Oi/Herzenberg work) at the Stanford University Laboratory as early as July 1978, later published in December of 1979.

The district court also held the claims of the '110 patent invalid for obviousness from the Oi/Herzenberg work in view of (1) a February 1979 article by M. E. Frankel and W. Gerhard (Frankel

article) which discloses high-affinity monoclonal antibodies, and apparently in view of numerous other references including (2) the work of Nobel Prize winners G. Kohler and C. Milstein disclosing a Nobel Prize-worthy method for producing monoclonal antibodies in vitro (outside the body) published in an August 7, 1975, article; (3) U.S. Patent No. 4,244,940 issued to Jeong et al. disclosing a simultaneous polyclonal assay (Jeong), U.S. Patent No. 4,098,876 to Piasio et al. disclosing a reverse polyclonal sandwich assay (Piasio), U.S. Patent No. 4,016,143 to Schurrs et al. disclosing a forward polyclonal sandwich assay (Schurrs); (4) a July 1979 publication by A. C. Cuello et al. disclosing the use of monoclonal antibodies in competitive assays; and (5) eight articles dated between January 1979 and March 6, 1980, "predicting" that monoclonal antibodies would be used in future immunoassays. [1]

[1] With respect to obviousness, one portion of the district court's opinion apparently relies on all of the above listed references, (1)-(5), for the obviousness holding while a later portion entitled "CONCLUSIONS OF LAW" relies on only the Oi/Herzenberg and Frankel articles. Furthermore, the district court did not state that the LJCRF work was considered for purposes of §103, although we recognize that §102(g) prior art can be used for §103.

The district court also invalidated the patent on various grounds based on 35 USC 112, first and second paragraphs, as hereinafter discussed.

A. *The References*

1. *Kohler and Milstein's Nobel Prize-Winning Work: Producing Monoclonal Antibodies In Vitro For the First Time*

In early immunoassay work, polyclonal antibodies produced in vivo (in the body) in mice were used to bind with the antigen to be detected in the body fluid sample. Mice were immunized by injection with antigen so that the lymphocytes in their bodies produced antibodies that attacked the injected antigen. Those polyclonal antibodies were *withdrawn* from the animal's blood and used in immunoassays. The major problem was that when the mice's immune systems changed or the mice died, the antibodies changed or died too; supply was limited and uncertain.

As the examiner was aware, Kohler and Milstein developed a technique not only for producing antibodies in vitro, independent of a living body, thus eliminating dependence on a particular animal, but for in vitro production of monoclonal antibodies by hybridomas, discussed in the Background section, supra.

Given that sandwich assays require enormous amounts of antibodies, companies like appellant and appellee, which utilize monoclonal antibodies for sandwich assays, would not be in business were it not for the work of Kohler and Milstein.

2. *The Work of Drs. Ruoslahti, Uotila, and Engvall at the La Jolla Cancer Research Foundation (LJCRF) in 1979 and 1980*

Dr. Ruoslahti performed mostly competitive immunoassays using polyclonal antibodies to alphafetoprotein (AFP) antigens at the City of Hope since 1970. Dr. Uotila joined him in late 1978 to perform immunoassays using monoclonal antibodies to AFP. After producing monoclonal antibodies to AFP and performing competitive radio immunoassays (RIA -- a competitive assay that uses a radioactive label) with monoclonal antibodies at the City of Hope in mid-1979, Drs. Ruoslahti, Uotila and Engvall left LJCRF.

In the fall of 1979, September or October according to Dr. Uotila, discussion and work began on using monoclonal antibodies to AFP in a sandwich assay. Dr. Uotila, the principal researcher in this particular endeavor, generated six notebooks while at the City of Hope and LJCRF. The next-to-last page of notebook four contained a note to Dr. Uotila from Dr. Ruoslahti reading:

> Sometime you should enzyme label a good monoclonal antibody so that you can set up a sandwich assay. If you use two monoclonal antibodies, you may be able to do the assay with a single incubation, since the monoclonal antibodies are likely to be
>
> **Page 85**
>
> directed against different determinants and not compete with one another.

Although Dr. Uotila's notebook pages were, for the most part, unsigned, undated, and uncorroborated, Dr. Ruoslahti's testimony, placed the date of this note at about October 1979 by referring to the first pages of notebook five which were dated in early November 1979. Dr. Ruoslahti testified that one curve on one graph on page 43D of notebook five showed a successful simultaneous sandwich assay using monoclonal antibodies about November 5, 1979, although no data supporting that graph could be found elsewhere in the notebook. He further testified that the affinity of the monoclonal antibodies used for that test was not calculated until 1980 but that the raw data necessary for that calculation was generated in 1979.

Dr. Uotila stated in her deposition (she did not testify at trial) that she started work on a sandwich assay using monoclonal antibodies between October 4 and the end of that month, 1979, and that she could not remember the procedure used nor was there enough information in her notebook, including page 43D, to refresh her memory. She did remember, although she continued work on this assay because the tests did not yield repeatedly good curves without which she would not publish her work, that the assay on page 43D was successful. Dr. Engvall testified about a discussion of Dr. Uotila's monoclonal antibody work with her while at the City of Hope and about first performing a sandwich assay after arriving at LJCRF in 1979.

3. *The Work of Drs. Oi and Herzenberg at the Stanford University Laboratory in 1978 Published in December 1979*

Drs. Oi and Herzenberg used monoclonal antibodies to "map" epitopes or determine the number and location of different antibody binding sites on a known quantity of IgE antigen by attaching to it an antibody bound to a carrier and exposing that antigen to other monoclonal antibodies. The antibodies either attached to epitopes on the antigen or were blocked from doing so by the other monoclonal antibodies, depending on the location and number of epitopes; if the epitopes on the antigen were too close together and the number of antibodies too great, few antibodies would bind to the antigen. Hybritech points out that both Dr. Herzenberg and Dr. Oi testified that *their work did not involve determining the presence or quantity of antigen,* that they had no idea what the affinities of the monoclonal antibodies used were, and that those values were never calculated.

One unsigned, unwitnessed page from three large laboratory notebooks, which Hybritech argues is insufficient because it does not identify the chemical reagents or protocol used, was relied on by Monoclonal to establish actual reduction to practice of the Oi/Herzenberg work in 1978 to establish a case of §102(g) prior invention by another. The district court agreed with Monoclonal that the Oi/Herzenberg work anticipated the claimed invention and, in addition, combined this work with the Frankel publication to hold that the claimed subject matter was obvious under §103.

4. *The Frankel Article: Monoclonal Antibodies Having Affinities of 10 9liters/mole*

Frankel describes an RIA (radioimmunoassay) method for the rapid determination of affinity constants for monoclonal antibodies produced from hybridomas. The article states that the assay used is applicable only to antibodies with binding constants of about 10 10liters/mole and discloses the binding constants for antibodies to several closely related strains of influenza virus.

The district court found that Frankel disclosed monoclonal antibodies having the affinity constants claimed in the '110 patent, 10 8to over 10 9liters/mole.

5. *The Cuello Article and the Jeong, Piasio, and Schurr Patents Considered by the Examiner*

Cuello, dated July 1979, states that it describes the usefulness of monoclonal antibodies in the characterization and localization of neurotransmitters such as Substance P, a peptide clearly associated with the transmission of primary sensory information in the spinal cord. The article discloses producing monoclonal antibodies from hybrid myelomas (hybridomas), their use in conventional radioimmunoassay techniques, and the benefits from doing so which flow from the ability to derive permanent cell lines capable of continuous production of highly specific antibodies.

The district court found that the examiner twice rejected all of the claims of the '110 patent based on Cuello alone or in combination with the Jeong, Piasio, and Schurr references which disclose various sandwich assays using polyclonal antibodies. The court also found that the examiner allowed the claims after they were amended to include the 10 8affinity limitation and after Richard Bartholomew, a Hybritech employee, submitted an affidavit alleging the advantages of using monoclonal rather than polyclonal antibodies in sandwich assays.

Apparently based on the testimony of Monoclonal's expert witness Judith Blakemore, a named inventor of the Jeong patent, manager of antibody programs at Bio-Rad Laboratories from 1975 to 1982, and currently manager of monoclonal antibody therapeutics at Cetus Corporation, a Hybritech competitor in immunoassay diagnostics, the district court stated

Page 86

that the "reasons for allowance were not well-founded because (1) the alleged advantages were expected as naturally flowing from the well-known natural characteristics of monoclonal antibodies . . .; (2) . . . were not significant . . .; or (3) were at best minor," although they were "*argued* to the examiner as if they were" important. These were Monoclonal's words from its pretrial submission adopted by the court.

6. *The References That "Predicted" the Use of Monoclonal Antibodies in Immunoassays*

The district court stated, again in Monoclonal's words, that "it is of the utmost importance" that the advantages of monoclonal antibodies were "predicted by a number of authorities," eight to be exact, not important enough to list here, after the Kohler and Milstein discovery and after monoclonal antibodies became available.

B. *The Claimed Subject Matter of the '110 Patent*

Hybritech argues that the district court's determination that there is no credible evidence of conception or reduction to practice of the '110 invention before May 1980 is error because Dr. David's laboratory notebooks, Nos. 21 and 24, clearly show successful sandwich assays using monoclonal antibodies in August, September, and October of 1979. At the least, argues Hybritech, the invention was conceived in January of 1979, long before Drs. Ruoslahti, Engvall, and Uotila began work on a sandwich assay using monoclonal antibodies, and diligence was thereafter exercised until constructive reduction to practice occurred by the filing of the '110 patent application on August 4, 1980.

Dr. David and Greene testified that pages 2118 to 2122 of Dr. David's notebook, dated January 4, 1979, and witnessed January 30, 1979, disclose the generic conception of the invention in the context of the physical support structure used to carry out a sandwich assay, and Dr. David testified on redirect that (1) Page 1128 of notebook 21, dated May 27, 1979, recorded an early attempt at a sandwich assay that failed, (2) on August 3, 1979, as recorded at page 1166, a sandwich assay using monoclonal antibody 068 attached to a solid carrier, a radio-labelled 068 antibody, and a hepatitis antigen from an Abbott Labs polyclonal competitive assay kit was successfully performed, and (3) a sandwich assay using a bound 259 antibody, a radio-labelled 068 antibody, and a hepatitis antigen was successfully performed on September 21, 1979. Hybritech also urges that work in October 1979 directed to determining whether certain monoclonal antibodies were recognizing the same or different determinants, was a reduction to practice.

Monoclonal points out that these notebook pages do not expressly state that monoclonal antibodies of 10 8liters/mole affinity were used in a sandwich assay and that the May, August, and September notebook entries were not witnessed until about the time Dr. Adams, experienced in patent matters, joined Hybritech and advised its researchers on properly recording laboratory work. They therefore claim that actual reduction to practice was not shown before May 1980.

OPINION

I. *Review Under Rule 52(a) Fed.R. Civ. P.*

Rule 52(a) "ensures care in the preparation of an opinion . . . and provides appellate courts with the benefit of the District Court's insights into a case," *Pentec, Inc. v. Graphic Controls Corp.,* 776 F.2d 309 318, 227 USPQ 766, 772 (Fed.Cir. 1985) (Harvey, Senior District Judge, concurring) by requiring a district court to "find the facts specially and state separately its conclusions of law thereon." With the exception of the first eight paragraphs, the first half of the district court's opinion here is Monoclonal's *pretrial* brief and the last three pages of the opinion are Monoclonal's *pretrial* findings of fact and conclusions of law. The district court adopted the above documents virtually verbatim, with the exception of portions of each concerning inequitable conduct and noninfringement, apparently without inviting a response from Hybritech, resulting in a repetitious (as the district court admitted in the opinion), sometimes internally inconsistent, and hard to follow opinion that presents us with a difficult task in gleaning the basis for many of the conclusions. For some of the findings, submitted before trial, no supporting evidence was introduced at trial.

The Supreme Court, in *Anderson v. City of Bessemer City, N.C.,* 105 S.Ct. 1504 (1985), strongly criticized the practice of "verbatim adoption of findings of fact prepared by prevailing parties, particularly when those findings have taken the form of conclusory statements unsupported by citation to the record." *Anderson,* supra at 1511. This court also has cautioned against the adoption of findings, especially when proposed by a party before trial, as here, and stated that the likelihood of clear error in those findings increases in such a situation. *Lindemann Maschinenfabrik v. American Hoist and Derrick,* 730 F.2d 1452, 1457, 221 USPQ 481, 485 (Fed.Cir. 1984).

Page 87

Notwithstanding our misgivings about whether the findings in this case, prepared before any evidence was introduced, satisfy the objectives of Rule 52(a) -- a carefully prepared opinion providing the reviewing court with the benefit of the district court's *reasoned insights* into the case -- those findings are the district court's and may be *reversed* only if clearly erroneous. *See Anderson,* supra, at 1511; *Lindemann,* 730 F.2d at 1457, 221 USPQ at 485.

"A finding is clearly erroneous when, although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." *United States v. United States Gypsum Co.,* 333 U.S. 364, 395 (1948). "This standard plainly does not entitle a reviewing court to reverse the finding of the trier of fact simply because it is convinced that it would have decided the case differently." *Anderson,* supra, at 1511. In other words, "if the district court's account of the evidence is plausible in light of the record viewed in its entirety" or "where there are two permissible views of the evidence," the factfinder cannot be clearly erroneous. *Anderson,* supra, at 1511 (quoting *United States v. Yellow Cab Co.,* 338 U.S. 338, 342 (1949)). This is so, stated the Court in dictum, *see Anderson,* supra, at 1516 (Blackmun, J., concurring), even when the district court's findings rest on physical or documentary evidence or inferences from other facts and not on credibility determinations. *See also* Rule 52(a) Fed.R.Civ.P. (as amended Aug. 1, 1985). If the latter are involved, "Rule 52 demands even greater deference to the trial court's findings" but a trial judge may not "insulate his findings from review by denominating them credibility determinations"; if documents or objective evidence contradict the witness' story, clear error may be found even in a finding purportedly based on a credibility determination. *Anderson,* supra, at 1512-13. We proceed in light of all these principles.

II. *Presumption of Validity*

Under 35 USC 282, a patent is presumed valid, and the one attacking validity has the burden of proving invalidity by clear and convincing evidence. *See, e.g., American Hoist & Derrick Co. v. Sowa & Sons, Inc.,* 725 F.2d 1350, 1360, 220 USPQ 763, 770 (Fed.Cir. 1984). Notwithstanding that the introduction of prior art not before the examiner may facilitate the challenger's meeting the burden of proof on invalidity, the presumption remains intact and on the challenger throughout the litigation, and the clear and convincing standard does not change. *See, e.g., Jervis B. Webb Co. v. Southern Systems, Inc.,* 742 F.2d 1388, 1392 & n.4, 222 USPQ 943 , 945 & n.4 (Fed.Cir. 1984). The only indication that the district court recognized the presumption of validity and its proper application was its statement that "[t]he key issue in this case is whether the defendant has overcome the presumption of nonobviousness." That statement, however, speaks only part of the truth; the presumption of validity goes to validity of the patent in relation to the patent statute *as* a *whole,* not just to nonobviousness under Section 103.

III. *Prior Invention of Another, 35 USC 102(g)*

Section 102(g) states that a person shall be entitled to a patent unless "before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it." Section 102(g) "relates to prior inventorship by another in this country" and "retains the rules governing the determination of priority of invention . . . . " *Kimberly-Clark Corp. v. Johnson & Johnson,* 745 F.2d 1437, 1444, 223 USPQ 603, 606 (Fed.Cir. 1984) (quoting P.J. Federico, *Commentary on the New Patent Act,* 35 USCA page 1, at 19 (1954)). Section 102(g) says: "In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other."

Reduction to practice, and conception as well, is a legal determination subject to review free of the clearly erroneous standard. *Barmag Barmer Maschinenfabrik AG v. Murata Machinery, Ltd,* 731 F.2d 831, 837, 221 USPQ 561, 565-66 (Fed.Cir. 1984); *D.L. Auld Co. v. Chroma Graphics Corp.,* 714 F.2d

1144, 1151, 219 USPQ 13, 18 (Fed.Cir. 1983). Findings of fact supporting that legal conclusion, are, of course, reviewed under the clearly erroneous standard.

Conception is the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice." 1 *Robinson On Patents* 532 (1890); *Coleman v. Dines,* 754 F.2d 353, 359, 224 USPQ 857, 862 (Fed.Cir. 1985). Actual reduction to practice requires that the claimed invention work for its intended purpose, *see, e.g., Great Northern Corp. v. Davis Core & Pad Co.,* 782 F.2d 159, 165, 228 USPQ 356, 358, (Fed.Cir. 1986), and, as has long been the law, constructive reduction to practice occurs when a patent application on the claimed invention is filed. *Weil v. Fritz,* 572 F.2d 856, 865 n.16,

Page 88

196 USPQ 600 , 608 n.16 (CCPA 1978) (citing with approval *Automatic Weighing Machine Co. v. Pneumatic Scale Corp.,* 166 F. 288 (1st Cir. 1909)).

[1] After a review of the record in its entirety, including the numerous corroborating Hybritech laboratory notebooks, internal documents, and pertinent testimony, we hold clearly erroneous the district court's finding that there is no clear or corroborated evidence "with regard to when before May 1980, the idea of actually using monoclonals in sandwich assays" was conceived or, more properly, of when the *claimed invention* was conceived, and therefore reverse the court's holding, as a matter of law, that Hybritech's inventors did not conceive the claimed invention before May 1980.

Hybritech's claim of conception, generally, is evidenced by the sometimes sparsely documented work of a start-up company whose first small advances evolved into the myriad activities of a mature company with efforts directed toward developing the claimed invention by first employing the Kohler and Milstein technology to produce the necessary monoclonal antibodies and using those antibodies in diagnostic sandwich assay kits. There is no doubt that exploiting monoclonal antibodies for use in sandwich assays was one of the major objectives of Hybritech. In a letter to Pharmacia Fine Chemicals dated April 26, 1979, Greene, in responding to Pharmacia's interest in Hybritech's products, outlined the latter's "efforts to bring the exciting new hybridoma technology into routine medical use" and its exploration of "several intriguing concepts for which monoclonals may open up new immunodiagnostic techniques heretofore infeasible with animal serums." Although company minutes in early 1979 contain little about the claimed subject matter and some of the discussions thereon, such as Greene's and Dr. Adams' conversation about monoclonal sandwich assays when the former was trying to woo Dr. Adams to join Hybritech were unrecorded, the Hybritech laboratory notebooks and the nature of Hybritech's research program fully corroborate the testimonial evidence of conception and thus clearly support our holding that Hybritech conceived the claimed invention before LJCRF.

Dr. David's January 1979 notebook describes, in detail, as explained by Greene and Dr. David at trial, a nylon apparatus that undoubtedly could be used for performing a sandwich assay using monoclonal antibodies, although Dr. David testified on cross-examination that at that time Hybritech had not yet developed any monoclonal antibodies, including attaching one of the reagents to a solid carrier ring, contacting that ring with a fluid sample in a microtiter plate well, adding a labelled reagent to the well after rinsing, and then "counting" or measuring the amount of either the labelled or unlabelled reagent after a prescribed time and second rinsing. The notebook then describes the procedure for detecting an antibody "(a-x)" to an antigen "(x)" complete with diagrams and text, both illuminated by Dr. David at trial. The notebook further states, "Alternatively, if one wished to quantitate an antigen, y, the identical procedure would be followed, except that reagents would be *reversed*, i.e. the reaction would be:" and there follows a clear illustration of an antibody attached to a solid carrier reacting with an antigen to form a complex, and that complex reacting with a second labelled antibody. The notebook was signed by Dr. David on January 4, 1979, and witnessed and signed on January 30 of the same year by Dr. Curry, the first cell biologist hired at Hybritech to set up the hybridoma production program.

Dr. David testified on direct that monoclonal antibodies were developed in the following months: antigens were purchased from outside sources and purified before being injected into mice; the spleen cells from those mice were fused with myelomas; and the resultant hybridomas were separated into well plates for development, and a radioimmunoassay procedure was carried out to determine the affinity of the antibodies.

The May 1979 failed sandwich assay, witnessed in May 1980, corroborates Dr. David's testimony that a polyclonal antibody bound to a solid carrier and a labelled monoclonal antibody were used in a

sandwich assay with an antigen from Abbott Labs' Ausria polyclonal diagnostic kit for hepatitis. No binding was detected.

Dr. David testified about the experiment documented in the August 1979 notebook, a sandwich assay with a hepatitis antigen from an Abbott Labs Ausria kit with two Hybritech 068 monoclonal antibodies, one attached to a solid carrier bead and the other labelled; the purpose of the experiment was to quantitate the antigen. The notebook corroborates Dr. David's testimony that the test was positive and lists the counts per minute of the labelled antibody. Defendant Monoclonal's expert Ciotti testified about this experiment:

> Also, of course, it is limited to -- it is limited to hepatitis antigen. And without a generic conception, it would just be merely a -- if it did work for its intended purpose -- which I would assume for purposes of discussion -- it *would be a reduction to practice of one embodiment.* And without a corresponding generic conception, I don't think it would be held to be the making of the invention in
>
> **Page 89**
>
> terms of, for instance, in claim 19. [Emphasis ours.]

Dr. David further testified that the September 21, 1979, record in David's notebook, witnessed months later, shows a reverse sandwich assay using a bound 259 monoclonal antibody and a labelled 068 monoclonal antibody with a hepatitis antigen with results confirmed by a dose response curve. [2] Hybritech further alleges that a laboratory notebook page dated October 1979 is a reduction to practice of the claimed invention but fails to cite any related testimony or other evidence in support thereof.

---

[2] A dose response curve is antigen concentration plotted against the signal produced by labelled antibody in an immunoassay. The signal increases with increasing antigen concentration in a successful assay but at some point decreases when the antigen concentration becomes too high.

Finally, the record shows that the claimed affinity limitation "of at least about 10 8liters/mole" was determined and appreciated during the course of the development of the claimed subject matter. Dr. David and Dr. Adams separately testified that the screening procedures used by Hybritech ensured that only monoclonal antibodies having at least 10 8liters/mole affinity would be used in assays. An October 1979 internal memorandum from Greene to the staff states "To improve comparisons we will express all affinities to the base ten to the eighth which represents the lower end of the useable range."

We are left with the definite and firm conviction that a mistake has been committed because the district court's account of the evidence that "there was no credible evidence of conception before May 1980" is insupportable. There is such evidence. The laboratory notebooks, alone, are enough to show clear error in the findings that underlie the holding that the invention was not conceived before May 1980. That some of the notebooks were not witnessed until a few months to one year after their writing does not make them incredible or necessarily of little corroborative value. Admittedly, Hybritech was a young, growing company in 1979 that failed to have witnesses sign the inventors' notebooks contemporaneously with their writing. Under a reasoned analysis and evaluation of all pertinent evidence, however, we cannot ignore that Hybritech, within a reasonable time thereafter, prudently had researchers other than those who performed the particular experiments witness the notebooks in response to Tom Adams' advice. The notebooks clearly show facts underlying and contemporaneous with conception of the claimed invention and in conjunction with the testimony of Dr. David and Greene, and others, are altogether legally adequate documentary evidence, under the law pertaining to conception, of the formation in the minds of the inventors of a definite and permanent idea of the complete and operative invention as it was thereafter applied in practice. We thus are not moved by Monoclonal's argument that the findings of fact underlying conception are based on credibility determinations and are more sacrosanct than usual. *See Anderson,* supra, at 1512-13.

1. *LJCRF Is Not Prior Art*

Hybritech laboratory notebooks and the uncontradicted testimony of Dr. David and Mr. Greene show that development of the claimed invention proceeded diligently through the rest of 1979 and 1980, there being absolutely no evidence of record nor even argument by Monoclonal that Hybritech was not

diligent in its efforts to reduce to practice the claimed invention during the period January 1979 to the '110 application filing date of August 4, 1980. We therefore hold as a matter of law that Hybritech's conception, which was before LJCRF conceived the claimed invention, coupled by diligence to its constructive reduction to practice by the filing of the '110 application, entitle Hybritech to priority over LJCRF. *See* 35 USC 102(g). The work of LJCRF is therefore not prior art.

We also note that there is inadequate factual basis for the district court's holding that LJCRF reduced the claimed invention to practice as early as November 1979 because the only evidence that corroborates the testimony of Ruoslahti, Uotila, and Engvall is the note from Ruoslahti to Uotila, see section A, 2, supra, which indisputably is not the claimed invention, and the *one* curve from *one* graph from only one page, 43D, of the six Uotila notebooks. After a reasoned examination, analysis, and evaluation of this pertinent evidence we conclude that it falls far short of showing the "formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice," *see Coleman,* 754 F.2d at 359, 224 USPQ at 862, and therefore is legally inadequate to support even a holding of *conception* of the claimed invention by LJCRF personnel in 1979.

(1) It is undisputed that page 43D was not signed, witnesed, or dated; (2) the deposition testimony of Uotila was that she could not remember the procedure used to arrive at the dose-response curve on page 43D and there was not enough information in her notebook to refresh her memory; (3) the testimony of

Page 90

Ruoslahti was that he could find *no* data in the notebook supporting that graph, none of the *later* graphs shown there represented successful assays and that "especially after this was done, we ran into more severe problems. And it took us a while to do away with the problems;" (4) Ruoslahti also testified that they never determined, in 1979, the affinities of the monoclonal antibodies they used, and that the title of page 43D had been altered at some point -- the word "inhibition" had been crossed out and "sandwich" written in; and (5) the testimony of Engvall was that there was nothing about the shape of those curves which indicates that they were sandwich assays. We also note, as evidence bearing upon the credibility of Ruoslahti's testimony (that LJCRF actually reduced the claimed invention to practice in 1979), that when LJCRF attempted to provoke an interference in the PTO with Hybritech based on the U.S. filing of an application that was the counterpart to a Swedish application disclosing similar subject matter, LJCRF could not demonstrate even a *prima facie* reduction to practice prior to Hybritech's August 4, 1980, filing date. During that proceeding, the earliest dates Ruoslahti set down on paper to support conception and reduction to practice were in 1980.

2. *The Work of Oi/Herzenberg Is Not the Claimed Invention*

[2] It is axiomatic that for prior art to anticipate under §102 it has to meet every element of the claimed invention, and that such a determination is one of fact. *See, e.g., Lindemann,* supra, 730 F.2d at 1458, 221 USPQ at 485; *Great Northern Corp. v. Davis Core & Pad Co.,* 782 F.2d 159, 165, 228 USPQ 356, 358 (Fed.Cir. 1986). Section 102(g) upon which the district court relied is one type of "anticipation," i.e., prior invention by another of the same invention. Drs. Oi and Herzenberg testified that their work did not involve detecting the presence of or quantitating antigen but a determination of the number and location of epitopes on a *known* quantity of antigen. Although this work did involve a sandwich assay to the extent that an antigen was sandwiched between two monoclonal antibodies, it is clear that the similarity between that work and the claimed invention goes no further. Furthermore, both doctors testified that they did not know the affinities of the antibodies that were used in their mapping work and in fact never calculated them. Ciotti, Monoclonal's expert, testified that the 10 8affinity limitation cannot be found anywhere in the Oi/Herzenberg work. Again we are left with a definite and firm conviction that a mistake was made because that work does not meet every element of the claimed invention. The district court's finding to the contrary is clearly erroneous.

We note that the district court, in also holding the patent invalid under §103, next considered, combined the Oi/Herzenberg work with the Frankel reference, one justifiable inference therefrom being that the court recognized that Frankel discloses a claim *element* that Oi/Herzenberg does not, namely, at least about 10 8liters/mole affinity.

IV. *Obviousness, 35 USC 103*

A section 103 obviousness determination -- whether the claimed invention *would have been* (not

"would be" as the court repeatedly stated because Monoclonal's pretrial papers used that improper language) obvious at the time the invention was made is reviewed free of the clearly erroneous standard although the underlying factual inquiries -- scope and content of the prior art, level of ordinary skill in the art, [3] and differences between the prior art and the claimed invention -- integral parts of the subjective determination involved in §103, are reviewed under that standard. Objective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered *before* a conclusion on obviousness is reached and is not merely "icing on the cake," as the district court stated at trial. *See Lindemann,* supra, 730 F.2d at 1461, 221 USPQ at 488; *Stratoflex, Inc. v. Aeroquip Corp.,* 713 F.2d 1530, 218 USPQ 871 (Fed.Cir. 1983); *Kansas Jack, Inc. v. Kuhn,* 719 F.2d 1144, 219 USPQ 857 (Fed.Cir. 1983); *W.L. Gore & Associates v. Garlock Inc.,* 721 F.2d 1540, 220 USPQ 303, 314 (Fed.Cir. 1983).

[3] Although the district court failed expressly to find the level of ordinary skill in the art at the time the invention was made, it did make reference to "[p]eople working in immunology aware of the Kohler and Milstein discovery" which we deem an accurate finding for the purposes of that portion of the *Graham* factual inquiries.

1. *The Eight Articles "Predicting" Widespread Use of Monoclonal Antibodies*

Before discussing the more pertinent references in this case -- the Oi/Herzenberg and Frankel works -- we cull the other prior art references relied on by the trial court.

[3] First, the latest four of the eight articles that the court stated were of the "utmost importance" because they "predicted" that the breakthrough in production of monoclonal antibodies by Kohler and Milstein would lead to widespread use of monoclonal antibodies in

Page 91

immunoassays are neither 102(a)/103 nor 102(b)/103 prior art because they are dated between late 1979 and March 6, 1980, well after the date of conception and within one year of the filing date of the '110 patent.

The earliest four of the eight articles, on the other hand, although clearly prior art, discuss *production* of monoclonal antibodies -- admittedly old after Kohler and Milstein showed how to produce them -- but none discloses sandwich assays. At *most,* these articles are invitations to try monoclonal antibodies in immunoassays but do not suggest how that end might be accomplished. To the extent the district court relied upon these references to establish that it would have been *obvious to try* monoclonal antibodies of 10 8liters/mole affinity in a sandwich immunoassay that detects the presence of or quantitates antigen, the court was in error. *See Jones v. Hardy,* 727 F.2d 1524, 1530, 220 USPQ 1021, 1026 (Fed.Cir. 1984) ("Obvious to try" is improper consideration in adjudicating obviousness issue). [4]

[4] Finding 10, which states that the invention was contemporaneously developed and disclosed in at least five publications and patent applications not listed above *and dated well after the filing date of the '110 patent but before its issuance* is irrelevant for purposes of the hypothesis based on the three factual inquiries required by §103 as interpreted by *Graham v. John Deere,* 383 U.S. 1, 148 USPQ 459 (1966) because obviousness must be determined as of the time the invention was made. Additionally, they are of little probative value in this case because they are dated December 1981 at the earliest, more than a year after the August 4, 1980, filing date here and roughly two years after conception occurred. Furthermore, simultaneous development may or may not be indicative of obviousness, the latter being the case here for the above reasons and because the other evidence of nonobviousness is adequate, such occurrences having been provided for in 35 USC 135. *Lindemann,* supra, 730 F.2d at 1460-61, 221 USPQ at 487; *Environmental Designs, Ltd. v. Union Oil Co. of California,* 713 F.2d 693, 698 n.7, 218 USPQ 865 , 869 n.7 (Fed.Cir. 1983)

2. *The Kohler and Milstein Work, the Cuello Article and the Jeong, Piasio, and Schurr Patents Considered by the Examiner*

The district court's finding that Kohler and Milstein developed a method for producing monoclonal antibodies in vitro is correct, but that finding proves no more; although it made possible all later work in that it paved the way for a supply of monoclonal antibodies, it indisputably does not suggest using

monoclonal antibodies in a sandwich assay in accordance with the invention claimed in the '110 patent.

The Cuello reference discloses monoclonal antibodies but not in a sandwich assay. The competitive assay in Cuello, moreover, uses only one monoclonal antibody and thus in no way suggests the claimed invention wherein a ternary complex of two monoclonal antibodies and an antigen form a sandwich. Furthermore, the court did not explain how this art, by itself or in combination with any of the other art, suggests the claimed subject matter and thus why that combination would have been obvious. We are of the opinion that it does not.

The district court correctly found that the use of polyclonal antibodies in sandwich assays was well known. The Jeong patent discloses the use of polyclonal antibodies in a simultaneous sandwich assay, with no suggestion that monoclonal antibodies be so used. It is prior art by virtue of §102(e), application for the patent having been filed September 5, 1978, its effective date as a reference. The Piasio patent, disclosing a reverse sandwich assay using polyclonal antibodies, and Schurrs, disclosing a forward sandwich assay using the same, both §102(a) prior art, are likewise devoid of any suggestion that monoclonal antibodies can be used in a similar fashion.

3. *The Oi/Herzenberg Work and the Frankel Article*

Clearly, the most pertinent items of prior art not cited by the examiner are the Oi/Herzenberg work, as described in section A, 3, supra, and the Frankel article. As stated in the discussion of Prior Invention of Another (section III, 2, supra), the Oi/Herzenberg work involved mapping epitopes on a known quantity of antigen. It was not concerned with and does not disclose using monoclonal antibodies of at least 10 8liters/mole affinity. Oi and Herzenberg testified that they did not know the affinity of the antibodies used, and Ciotti testified that nowhere in that work is there mention of monoclonal antibody affinity of at least 10 8liters/mole. On this basis, we conclude that the Oi/Herzenberg work is qualitatively different than the claimed invention; the former is directed to mapping epitopes on a known quantity of antigen and the latter to determining the "presence or concentration of an antigenic substance in a sample of fluid . . . . " We disagree with Monoclonal that these are "essentially the same thing." Furthermore, it is perfectly clear that this work in no way suggests using monoclonal antibodies of the affinity claimed in the '110 patent. It is because of these differences between the Oi/Herzenberg work and the claimed invention that the fact that an antigen was sandwiched between two monoclonal antibodies in the course of Oi's and Herzenberg's work is not sufficient basis to conclude that the claimed invention would have been obvious at the time it was made to a person of ordinary skill in the art.

Likewise, a conclusion that the invention would have been obvious cannot properly be reached when the Oi/Herzenberg work is

Page 92

considered in view of the Frankel article. Frankel teaches a method for rapid determination of affinity constants for monoclonal antibodies, some of which clearly have affinities of the order defined by the claims, but does not in any way suggest using two of those antibodies in a sandwich to assay an antigen by forming a ternary complex of labelled antibody, the antigenic substance, and a bound antibody wherein the presence of the antigenic substance is determined by measuring either the amount of labelled antibody bound to a solid carrier or the amount of unreacted labelled antibody. The mere existence of prior art disclosing how to measure the affinity of high affinity monoclonal antibodies is insufficient to support a holding of obviousness. Hybritech's claims define a *process* that *employs* monoclonal antibodies, and does not merely claim antibodies of high affinity. In view of the fact that the Oi/Herzenberg work is not directed to an assay as claimed and does not disclose antibodies of at least 10 8liters/mole affinity, and further that Frankel fails to suggest using such antibodies in a sandwich assay, the Frankel article does not compensate for the substantial difference between the Oi/Herzenberg work and the claimed subject matter, and therefore those references in combination cannot support a holding of obviousness.

4. *Objective Evidence of Nonobviousness*

[4] In one part of its opinion the court found that "the commercial success of the kits *may* well be attributed to the business expertise and acumen of the plaintiff's personnel, together with its capital base and marketing abilities" (emphasis ours) and later that "[w]here commercial success is based on the sudden availability of starting materials, in this instance the availability of monoclonal antibodies

as a result of the Kohler and Milstein discovery, business acumen, marketing ability, and capital sources, no causal relationship is proven." (Citation omitted.)

i. *Commercial Success: Hybritech's Diagnostic Kits Grabbed a Substantial Market Share*

The undisputed evidence is that Hybritech's diagnostic kits had a substantial market impact. The first diagnostic kit sales occurring in mid-1981, sales increased seven million dollars in just over one year, from $6.9 million in-1983 to an estimated $14.5 million in 1984; sales in 1980 were nonexistent. Competing with products from industry giants such as Abbott Labs, Hoffman LaRoche, Becton-Dickinson, and Baxter-Travenol, Hybritech's HCG kit became the market leader with roughly twenty-five percent of the market at the expense of market shares of the other companies. Its PAP kit ranks second only to a product sold by Dupont's New England Nuclear, surpassing products from Baxter-Travenol, Abbott, and others. Hybritech's other kits, indisputably embodying the invention claimed in the '110 patent, obtained similar substantial market positions.

Although the district court did not provide its insights into why commercial success was due to business acumen and not to the merits of the claimed invention, Monoclonal urges in support that it was due to Hybritech's spending disproportionate sums on marketing, 25-30% of income. The undisputed evidence was that expenditures of *mature* companies in this field are between 17 and 32%. Furthermore, the record shows that advertising makes those in the industry -- hospitals, doctors, and clinical laboratories -- aware of the diagnostic kits but does not make these potential users buy them; the products have to work, and there is no evidence that that is not the case here or that the success was not due to the merits of the claimed sandwich assays -- clearly contrary to the district court's finding.

The trial court's finding that the "sudden availability of monoclonals" was the reason for the commercial success of Hybritech's diagnostic kits (Finding 11) is unsupported by the record and clearly erroneous. Monoclonal admits that monoclonal antibodies were available in the United States in *1978,* and the evidence clearly reflects that. Thus, at least *three years* passed between the time monoclonal antibodies were available in adequate supply and the time Hybritech began selling its kits. Especially in the fast-moving biotechnology field, as the evidence shows, that is anything but sudden availability.

ii. *Unexpected Advantages*

Hybritech points to the testimony of three witnesses skilled in the diagnostic field who state that, based on tests done in their laboratories as a result of real-world comparisons in the normal course of research, the diagnostic kits that embody the '110 invention unexpectedly solved longstanding problems. Dr. Hussa, the head of a large referral laboratory and a world-wide consultant, testified that until Hybritech introduced its kits, he and others were very skeptical and had almost exclusively used competitive assays with a radioactive tracer (RIAs). [5] In relation to an HCG Hybritech

Page 93

kit, he testified that he had first thought that the Hybritech HCG kit would not give accurate results for low antigen concentrations because that condition is indicated in the Hybritech kit by a low radioactivity reading, a reading difficult to differentiate from control samples containing no antigen. He also stated that in the past, RIA kits falsely detected HCG in nonpregnant women, a condition which would indicate cancer and surgery. He stated that when he employed the Hybritech HCG kit in such instances it demonstrated, correctly and absent any difficulty interpreting the data, that no HCG was present.

---

[5] Monoclonal's expert Blakemore testified that of 425 assays on the market in 1979 less than 1% were sandwich assays. Today, sandwich assays constitute the majority of all assays sold.

The record also shows that Blakemore, who testified extensively for Monoclonal that the claimed invention would have been obvious, never used monoclonal antibodies in sandwich assays at Cetus before 1980. Additionally, she did not even mention them in the Jeong patent, of which she was a coinventor, which issued January 13, 1981, long after the beginning of Hybritech's work in this area in 1979.

Dr. Blethen, an M.D. holding a Ph.D. in biochemistry, testified that she did not think that the Hybritech HGH kit, for detecting growth hormone in children, would offer any advantage, but she determined

that it detected HGH deficiencies in children where conventional RIAs failed to do so. She also stated that the kit does not give false positive readings as do conventional RIA kits, an opinion shared by Dr. Hussa. A third witness, Dr. Herschman, who holds a master's degree in chemistry, testified that he spent years working on the development of an assay that would determine the presence of TSH (thyroid stimulating hormone) with greater sensitivity. He succeeded but discovered that the Hybritech TSH kit had the same sensitivity, the test being performed in four hours rather than the three days his kit required.

Having considered the evidence of nonobviousness required by §103 and *Graham,* supra, we hold, as a matter of law, that the claimed subject matter of the '110 patent would not have been obvious to one of ordinary skill in the art at the time the invention was made and therefore reverse the court's judgment to the contrary. The large number of references, as a whole, relied upon by the district court to show obviousness, about twenty in number, skirt all around but do not as a whole suggest the claimed invention, which they must, to overcome the presumed validity, *Lindemann,* 730 F.2d at 1462, 221 USPQ at 488, *as a whole. See* 35 USC 103; *Jones v. Hardy,* 727 F.2d 1524, 1529, 220 USPQ 1021, 1024 (Fed.Cir. 1984). Focusing on the obviousness of substitutions and differences instead of on the invention as a whole, as the district court did in frequently describing the claimed invention as the mere substitution of monoclonal for polyclonal antibodies in a sandwich assay, was a legally improper way to simplify the difficult determination of obviousness. *See generally Hodosh v. Block Drug Co,* 786 F.2d 1136, 229 USPQ 182 (Fed.Cir. 1986). [6]

---

[6] It bears repeating that it is crucial that counsel set forth the law accurately. More particularly, it is the duty of counsel to impart to the judge that the obviousness question properly is whether the *claimed* invention *as a whole would have been* obvious to one of *ordinary* skill in the art *at the time the invention was made,* and that the district court must *expressly* make the three factual determinations required by *Graham* and consider objective evidence of obviousness *before* the legal conclusion of obviousness vel non is made. Submitting to the court language like "any differences . . . would have been obvious," as was done here, violates the axiom that the question is not whether the differences would have been obvious but the claimed invention *as a whole.* Furthermore, arguing that "it would be obvious" rather than that it would *have been* obvious shifts the court's focus to the wrong period of time, namely to a time long after the invention was made, in which, more likely than not, the prior art and the level of ordinary skill in the art are more advanced. *See* 35 USC 103.

With respect to the objective indicia of nonobviousness, while there is evidence that marketing and financing played a role in the success of Hybritech's kits, as they do with any product, it is clear to us on the entire record that the commercial success here was due to the merits of the claimed invention. It cannot be *argued* on this record that Hybritech's success would have been as great and as prolonged as admittedly it has been if that success were not due to the merits of the invention. The evidence is that these kits compete successfully with numerous others for the trust of persons who have to make fast, accurate, and safe diagnoses. This is not the kind of merchandise that can be sold by advertising hyperbole.

V. *Enablement, Best Mode, and Definiteness Under §112*

The section 112 defense appears to have been an afterthought of both Monoclonal, who briefly but unsuccessfully attempts to defend this utterly baseless determination, and of the district court which adopted the defense from Monoclonal's pretrial papers apparently without knowledge of the applicable law, to highlight, as it stated at trial, that it was part of its job to see that "whoever wins wins all the way or whoever loses loses all the way." Taken as a whole, the court's comments on §112 -- split into two parts, one from Monoclonal's pretrial brief and the other from the adopted pretrial

Page 94

findings and conclusions -- are internally inconsistent. The opinion states that the patent fails to disclose how (1) to make monoclonal antibodies; (2) to screen for proper monoclonal antibodies; and (3) to measure monoclonal antibody affinity and therefore the specification is nonenabling and does not satisfy the best mode requirement, and the claims are indefinite. We discuss each of these in turn.

1. *Enablement*

Enablement is a legal determination of whether a patent enables one skilled in the art to make and use the claimed invention, *Raytheon Co. v. Roper Corp.,* 724 F.2d 951, 960, 220 USPQ 592, 599

(Fed.Cir. 1983), is not precluded even if some experimentation is necessary, although the amount of experimentation needed must not be unduly extensive, *Atlas Powder Co. v. E.I. Du Pont De Nemours & Co.*, 750 F.2d 1569, 1576, 224 USPQ 409, 413 (Fed.Cir. 1984), and is determined as of the filing date of the patent application, which was August 4, 1980. *See W.L. Gore and Associates v. Garlock, Inc.*, 721 F.2d 1540, 1556, 220 USPQ 303, 315 (Fed.Cir. 1983). Furthermore, a patent need not teach, and preferably omits, what is well known in the art. *Lindemann,* 730 F.2d at 1463, 221 USPQ at 489.

The record fully supports the '110 patent's statement that

> The monoclonal antibodies used for the present invention are obtained by the [hybridoma] process discussed by Milstein and Kohler. . . . The details of this process are well known and not repeated here.

The district court itself stated that the "method for producing monoclonal antibodies in vitro was well known prior to the alleged invention of the '110 patent," and used the "sudden availability of monoclonal antibodies" produced by the Kohler and Milstein discovery to support, albeit erroneously, its finding of a lack of nexus between the merits of the claimed invention and its commercial success. The court then about-faced and held the '110 patent deficient because it fails to teach how to make monoclonal antibodies.

With respect to screening, the only permissible view of the evidence is that screening methods used to identify the necessary characteristics, including affinity, of the monoclonal antibodies used in the invention were known in the art and that the '110 patent contemplated one of those. At trial, Monoclonal's counsel stated "it is a procedure that was known in '78." In similar fashion, the district court held that the claimed subject matter would have been obvious in part because the "existence of monoclonal antibodies *having the affinity constants claimed in the patent was well known* prior to the alleged invention . . . ." [Emphasis ours.] Furthermore, there was not a shred of evidence that undue experimentation was required by those skilled in the art to practice the invention. We hold as a matter of law that the '110 patent disclosure is enabling.

2. *Best Mode*

"The specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 USC 112. Because not complying with the best mode requirement amounts to concealing the preferred mode contemplated by the applicant at the time of filing, in order to find that the best mode requirement is not satisfied, it must be shown that the applicant knew of and concealed a better mode than he disclosed. *DeGeorge v. Bernier,* 768 F.2d 1318, 1324, 226 USPQ 758, 763 (Fed.Cir. 1985) (quoting with approval *In re Sherwood,* 613 F.2d 809, 204 USPQ 537 (CCPA 1980)). The only evidence even colorably relating to concealment is testimony by various Hybritech employees that sophisticated, competent people perform the screening and that the screening process is labor-intensive and time-consuming. It is not plausible that this evidence amounts to proof of concealment of a best mode for screening or producing monoclonal antibodies for use in the claimed '110 process, and therefore we are of the firm conviction that the district court's finding that the best mode requirement was not satisfied is clearly erroneous.

3. *Indefiniteness*

[5] The basis of the district court's holding that the claims are indefinite is that "they do not disclose how infringement may be avoided because antibody affinity cannot be estimated with any consistency." (Conclusion 6.) Even if the district court's finding in support of this holding -- that "there is no standard set of experimental conditions which are used to estimate affinities" -- is accurate, under the law pertaining to indefiniteness -- "if the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits, the courts can demand no more," *Shatterproof Glass Corp. v. Libbey Owens Ford Co.,* 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed.Cir. 1985) -- the claims clearly are definite. The evidence of record indisputably shows that calculating affinity was known in the art at the time of filing, and

Page 95

notwithstanding the fact that those calculations are not precise, or "standard," the claims, read in light of the specification, reasonably apprise those skilled in the art and are as precise as the subject matter permits. As a matter of law, no court can demand more.

VI. *Motions*

Monoclonal's motion to strike Appendices A and B of Hybritech's reply brief as being beyond the page limit applicable to reply briefs is granted as to Appendix A but denied as to Appendix B, the latter having been helpful in culling the often non-supportive citations to the record by Monoclonal.

Hybritech's motion to supplement the record with a Monoclonal advertisement not considered at trial is denied. Any adverse impact that the disposition of these two motions has upon either party is more than outweighed by this court's patience with the seemingly endless flow of post-argument argumentative papers.

VII. *Conclusion*

The judgment of the district court holding the patent in suit invalid is reversed in all respects, and the case is remanded for a determination of the issue of infringement which the court held was moot.

REVERSED AND REMANDED

- End of Case -

ISSN 1526-8535

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > In re Gorman, 18 USPQ2 Cir. 1991)

18 USPQ2d 1885

In re Gorman

U.S. Court of Appeals Federal Circuit

No. 90-1362

Decided May 13, 1991

933 F2d 982

Headnotes

PATENTS

[1] Patentability/Validity - Obviousness - Combining references (▶ 115.0905)

Patent and Trademark Office's reliance on teachings of large number of references in rejecting patent application for obviousness does not, without more, weigh against holding of obviousness on appeal, since criterion is not number of references, but whether references are in fields which are same as or analogous to field of invention, and whether their teachings would, taken as whole, have made invention obvious to person skilled in that field.

[2] Patentability/Validity - Construction of claims (▶ 115.03)

Patentability/Validity - Obviousness - In general (▶ 115.0901)

Claim which describes features of invention in great detail is nevertheless obvious in view of prior art, since claim that is narrowly and specifically drawn must still meet requirements of 35 USC 103, and details listed in claim are shown in references and thus do not contribute to unobviousness.

[3] Patentability/Validity - Obviousness - Relevant prior art - Particular inventions (▶ 115.0903.03)

Patentability/Validity - Obviousness - Combining references (▶ 115.0905)

Application claim for candy sucker on stick, molded in elastomeric mold in shape of human thumb, is obvious in view of prior art, since all elements of claim, including molded lollipop having chewing gum base plug, with elastomeric mold serving as product wrapper, and candy in shape of human thumb, are shown in prior art references in various subcombinations, used in same manner and for same purpose as in claimed invention.

Case History and Disposition

Page 1886

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Jeffrey B. Gorman and Marilyn Katz, serial no. 06/882,480 (composite food product). From decision of Board of Patent Appeals and Interferences upholding examiner's rejection of all claims in application, applicants appeal. Affirmed.

Attorneys

Thomas W. Tolpin, Highland Park, Ill., for appellant.

Teddy S. Gron, associate solicitor (Fred E. McKelvey, solicitor, with him on brief), for appellee.

Judge

Before Rich, Newman, and Rader, circuit judges.

Opinion Text

Opinion By:

Newman, J.

Jeffrey B. Gorman and Marilyn Katz (hereinafter "Gorman") appeal the decision of the United States Patent and Trademark Office, Board of Patent Appeals and Interferences (the "Board") denying patentability to all the claims of Gorman's patent application Serial No. 06/882,480, entitled "Composite Food Product." We affirm.

The Invention

The claimed invention is a composite candy sucker on a stick, molded in an elastomeric mold in the shape of a human thumb. During the manufacturing process liquid candy is poured into the mold, and an edible plug of bubble or chewing gum or chocolate or food-grade wax is poured into the mold after the candy has hardened, serving as a seal for the end portion of the candy. A paper or plastic disc abuts and covers the plug. The mold serves as a cover that can be removed from the candy by means of protruding flanges. The cover is described as a "toy and novelty item".

Figure 1 shows the invention in the form in which it is marketed. Figure 2 shows the cover partially removed to reveal the candy portion (12) and the chewable or edible plug (58):

The claims describe the product in detail, as is apparent from claim 16, the claim pressed by Gorman in this appeal:

16. A composite food product, comprising:

> a candy core, said candy core being in a generally liquified form when formulated, heated, blended and poured into a mold and in a substantially thumb-shaped hardened form when cooled and removed from said mold;
>
> said thumb-shaped hardened form comprising said candy core positioned along a vertical axis and comprising a rigid joint-shaped portion, a rigid upper portion extending upwardly from said rigid joint-shaped portion along said vertical axis, and a rigid lower portion extending downwardly from said rigid joint-shaped portion along said vertical axis, said upper portion having a rigid finger nail-shaped portion with an upper rigid tip providing a rigid top end of said thumb-shaped hardened form and a rigid convex back extending rearwardly and downwardly from said rigid tip, and said rigid lower portion having a rigid bottom end and defining a recessed opening comprising a handle-receiving socket about said vertical axis;
>
> a removable resilient shell comprising a substantially thumb-shaped, elastomeric material selected from the group consisting of rubber and flexible plastic, said shell providing
>
> a mold for receiving and molding said liquified candy form,
>
> a removable outer protective cover positioned about and covering said hardened form comprising said candy core, and
>
> a toy and novelty item for placement upon the thumb of the user when removed from said hardened form comprising said candy core;
>
> said thumb-shaped elastomeric material comprising said removable resilient shell comprising a flexible joint-shaped portion, a flexible upper portion extending upwardly from said flexible joint-shaped portion along said vertical axis, and a flexible lower portion extending downwardly from said flexible joint-shaped portion along said vertical axis, said upper portion having a flexible finger nail-shaped portion with an upper flexible tip providing a flexible top end of said shell and a flexible convex back extending rearwardly and downwardly from said flexible tip, and said flexible lower portion having an enlarged open ended diverging base, said base having a larger circumference and transverse cross-sectional area than other portions of said shell and providing the bottom of said shell, said open ended base defining a plug-receiving chamber and an access opening for entrance of

said liquified form and discharge of said hardened candy form, and a set of substantially symmetrical arcuate lobes extending radially outwardly from said base, said lobes being circumferentially spaced from each other and providing manually grippable flange portions to facilitate manual removal of said shell from said core;

a plug positioned in said plug-receiving chamber adjacent said bottom of said shell, said plug abutting against the bottom of said core and providing a cap for substantially plugging and sealing the open end of said mold and cover to help enclose said candy core, and said plug comprising a food grade material selected from the group consisting of bubble gum, chewing gum, chocolate, and food grade wax;

a handle having a connecting portion connected to said plug and said candy core and positioned in said plug-receiving opening and having a manually grippable handle portion extending downward from said connecting portion along said vertical axis; and

a substantially planar annular disk for abuttingly engaging and removably seating against said base and said lobes adjacent said plug, said disk defining a central axial hole for slidably receiving said handle portion and having an outer edge with a maximum span larger than said access opening but less than the maximum diameter of said symmetrical set of lobes to substantially minimize the interference with manually gripping of said manual grippable flange portions of said lobes, said disk being of a material selected from the group consisting of paper, paperboard, and plastic, and providing a removable closure member and seal for substantially closing said access opening and sealing said plug and said candy core within said shell.

The claims were rejected in view of thirteen references. The primary references, patents to Siciliano, Copeman, and Pooler, show ice cream or candy molded in a plastic, rubber or elastomeric mold. In Siciliano and Copeman the mold also serves as the product wrapper. In Siciliano the ice cream is poured into the mold, a stick is inserted, the ice cream is hardened, and a cardboard cover seals the area between the stick and the elastomeric wrapper. Copeman and Kuhlke show candy lollipops molded in elastomeric molds. Copeman states that the mold may take "varying shapes, such as in the form of fruit, or animals" and Kuhlke discusses the desirability of sealing candy from the outside air. In Siciliano, Copeman and Kuhlke, the mold is peeled from the confection prior to use.

The two Nolte patents teach that gripping flanges may be placed on an ice cream wrap

Page 1888

per to facilitate removal. Ahern and Knaust each show a disc-shaped seal or cover for a frozen confection. Ahern shows the cover in conjunction with ice cream on a stick.

Harris shows a hollow thumb-shaped lollipop into which the thumb is inserted, and Craddock shows a thumb-shaped confection supported on a disc-shaped handle; in both cases without the other elements shown by Gorman. Fulkerson shows a candy coating surrounding a block of ice cream, and a candy plug for retaining liquid syrup inside a cavity in the ice cream. Webster shows chewing gum entirely enclosing a liquid syrup product. Spiegel shows a chocolate layer having an alcohol diffusion barrier to plug the end of a plastic container of liqueur. Fulkerson, Webster and Spiegel all suggest the greater appeal to consumers of providing two different components in the same confection.

The Board found that all of the features of Gorman's product were known to the art, and that various combinations of these elements existed in known similar structures. The Board concluded that the applicant's claimed combination was suggested by and would have been obvious in light of the references.

Discussion

A

Each element of the Gorman claims is in the prior art, separately or in sub-combination. Gorman argues that when it is necessary to combine the teachings of a large number of references in order to support a rejection for obviousness under 35 U.S.C. §103, this of itself weighs against a holding of obviousness.

[1] The criterion, however, is not the number of references, but what they would have meant to a person of ordinary skill in the field of the invention. In *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383, 231 USPQ 81, 93 (Fed.Cir. 1986), cert. denied, 480 U.S. 947 (1987), the court

held that a combination of about twenty references that "skirt[ed] all around" the claimed invention did not show obviousness. In other instances, on other facts, we have upheld reliance on a large number of references to show obviousness. Compare *In re Miller,* 159 F.2d 756, 758-58, 72 USPQ 512, 514-15 (CCPA 1947) (rejecting argument that the need for eight references for rejection supported patentability) with *Kansas Jack, Inc. v. Kuhn,* 719 F.2d 1144, 1149, 219 USPQ 857, 860 (Fed.Cir. 1983) (where teachings relied upon to show obviousness were repeated in a number of references, the conclusion of obviousness was strengthened). *See also, e.g., In re Troiel,* 274 F.2d 944, 947, 124 USPQ 502, 504 (CCPA 1960) (rejecting appellant's argument that combining a large number of references to show obviousness was "farfetched and illogical").

Determination of whether a new combination of known elements would have been obvious to one of ordinary skill depends on various facts, including whether the elements exist in "analogous art", that is, art that is reasonably pertinent to the problem with which the inventor is concerned. *In re Deminski,* 796 F.2d 436, 442, 230 USPQ 313, 315 (Fed.Cir. 1986). When the references are all in the same or analogous fields, knowledge thereof by the hypothetical person of ordinary skill is presumed, *In re Sernaker,* 702 F.2d 989, 994, 217 USPQ 1, 5 (Fed.Cir. 1983), and the test is whether the teachings of the prior art, taken as a whole, would have made obvious the claimed invention. *See In re Young,* 927 F.2d 588, 591, 18 USPQ2d 1089, 1091 (Fed.Cir. 1991).

When it is necessary to select elements of various teachings in order to form the claimed invention, we ascertain whether there is any suggestion or motivation in the prior art to make the selection made by the applicant. *Interconnect Planning Corp. v. Feil,* 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed.Cir. 1985). "'Obviousness can not be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination.'" *In re Bond,* 910 F.2d 831, 834, 15 USPQ2d 1566, 1568 (Fed.Cir. 1990) (quoting *Carella v. Starlight Archery and Pro Line Co.,* 804 F.2d 135, 140, 231 USPQ 644, 647 (Fed.Cir. 1986)).

The extent to which such suggestion must be explicit in, or may be fairly inferred from, the references, is decided on the facts of each case, in light of the prior art and its relationship to the applicant's invention. As in all determinations under 35 U.S.C. §103, the decisionmaker must bring judgment to bear. It is impermissible, however, simply to engage in a hindsight reconstruction of the claimed invention, using the applicant's structure as a template and selecting elements from references to fill the gaps. *Interconnect Planning,* 774 F.2d at 1143, 227 USPQ at 551. The references themselves must provide some teaching whereby the applicant's combination would have been obvious.

Page 1889

B

Gorman argues that the references showing ice cream in a mold or wrapper on a stick and the references showing candy in a mold or wrapper on a stick are not analogous, for they require different conditions of production. However, the Copeman reference shows the close relationship of these arts, stating that his elastomeric mold may be used for "frozen confections and other solid confections". We conclude that the ice cream on a stick and candy on a stick arts are analogous, and that the Siciliano, Copeman, Pooler, and Kuhlke references show or suggest Gorman's candy on a stick and covered with an elastomeric mold, for which the thumb-shape is shown by Harris or Craddock.

The suggestion of providing a layer of chewing gum, chocolate or the like, surrounding the candy core in the area not covered by the mold, to seal the candy and provide a second food product, is provided by Fulkerson, Webster, or Spiegel. The paper disc adjacent the base of the candy structure is shown in Ahern and Knaust. Harris and Craddock both show thumb-shaped candy. Gorman argues that the prior art does not suggest using the thumb-shaped cover as a toy after the candy is removed. However, Copeman states that his rubber mold may be used as a "toy balloon" after the candy is removed. Gorman argues that Craddock teaches away from the claimed invention because of Craddock's admonition that lollipops on sticks are dangerous to children. However, candy on a stick is too well known for this caution to contribute to unobviousness.

[2] Claim 16 recites details such as a "joint-shaped portion", a "finger nail portion", an "upper portion", a "lower portion" and a "convex back", as descriptive of the thumb shape. Such details are shown in the references and do not contribute to unobviousness. A claim that is narrowly and specifically drawn must nevertheless meet the requirements of §103:

> The mere fact that a claim recites in detail all of the features of an invention (i.e., is a "picture claim") is never, in itself, justification for the allowance of such a claim.

Manual of Patent Examining Procedure, §706 (Rev. 6, Oct. 1987) at p. 700-6; *In re Romito,* 289 F.2d 518, 129 USPQ 359 (CCPA 1961) (rejecting a "picture claim").

[3] Applying the principles of *Graham v. John Deere & Co.,* 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), we discern all of the elements of claim 16, used in substantially the same manner, in devices in the same field of endeavor. The various elements Gorman combined: the molded lollipop with a chewing gum plug, with the mold serving as the product wrapper; and candy in the shape of a thumb; are all shown in the cited references in various sub-combinations, used in the same way, for the same purpose as in the claimed invention. The Board did not, as Gorman argues, pick and choose among isolated and inapplicable disclosures in the prior art. Rather, the claim elements appear in the prior art in the same configurations, serving the same functions, to achieve the results suggested in prior art. *In re Sernaker,* 702 F.2d at 994, 217 USPQ at 5. The large number of cited references does not negate the obviousness of the combination, for the prior art uses the various elements for the same purposes as they are used by appellants, making the claimed invention as a whole obvious in terms of 35 U.S.C. §103.

The Board's decision is *AFFIRMED.*

- End of Case -

ISSN 1526-8535

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > In re Dow Chemical Co., 1529 (Fed. Cir. 1988)

5 USPQ2d 1529

In re Dow Chemical Co.

U.S. Court of Appeals Federal Circuit

No. 87-1406

Decided January 25, 1988

837 F2d 469

Headnotes

PATENTS

[1] Patentability/validity -- Obviousness -- Evidence of (► 115.0903)

Patentability/validity -- Obviousness -- Secondary considerations (► 115.0907)

Board of Patent Appeals and Interferences erred in rejecting as obvious claims for invention of impact resistant rubber-based resin suitable for molding and extrusion containing preferred ingredients styrene, maleic anhydride, and synthetic diene rubbers, since none of prior art references cited by patent holder and PTO suggest that any process could be used successfully in such three-component system to produce resin having desired properties, and since board did not give fair evidentiary weight to expert's skepticism concerning invention, or to five to six years necessary to produce invention, in determining obviousness issue.

Particular Patents -- Chemical -- Rubber Based Resins

3,919,354, Moore, Lehrer, Lyons and McKeever, impact resistant polymers of a resinous copolymer of an alkenyl aromatic monomer and unsaturated dicarboxylic anhydride, holding of obviousness *reversed*.

Case History and Disposition

Page 1529

Appeal from the U.S. Patent and Trademark Office Board of Patent Appeals and Interferences.

Reexamination of Patent No. 3,919,354, held by The Dow Chemical Company. From decisions rejecting all claims of patent as obvious, patent holder appeals. Reversed.

Attorneys

Douglas N. Deline, Midland, Mich. (Berndt W. Sandt with him on the brief) for appellant.

John H. Raubitschek, associate solicitor, Arlington, Va. (Joseph F. Nakamura, solicitor, and Fred E. McKelvey, deputy solicitor, with him on the brief) for appellee.

Judge

Before Smith, Nies, and Newman, Circuit Judges.

Opinion Text

Opinion By:

Newman, Circuit Judge.

Dow Chemical Company appeals the decisions of the United States Patent and Trademark Office Board of Patent Appeals and Interferences, No. 86-3426 (Feb. 25, 1987) and No. 662-81 (Mar. 25, 1986), together rejecting all the claims on reexamination of United States Patent No. 3,919,354 entitled "Impact Resistant Polymers of a Resinous Copolymer of an Alkenyl Aromatic Monomer and an Unsaturated Dicarboxylic Anhydride.". We reverse.

The Rejection

The invention is an impact resistant rubber-based resin having improved resistance to heat distortion. Claim 28, the broadest claim on appeal, is illustrative:

> 28. A polymer suitable for molding and extrusion, of substantially improved resistance to mechanical shock and impact, the polymer consisting essentially of the polymerization product of
>
> a. a monovinyl alkenyl aromatic monomer containing up to 12 carbon atoms and having the alkenyl group attached directly to the benzene nucleus, the al kenyl aromatic compound being present in a proportion of from about 65 to 95 parts by weight and from 35 to 5 parts by weight of an unsaturated dicarboxylic acid anhyride readily copolymerizable therewith, and
>
> b. from 5 to 35 parts by weight of a diene rubber per 100 parts of (a) plus (b), the rubber consisting essentially of 65 to 100 weight percent butadiene, or isoprene and up to 35 weight percent of an alkenyl aromatic hydrocarbon as the sole other monomer in the rubber, the rubber having a glass temperature not higher than 0°C., the rubber being in the form of a plurality of particles having diameters within the range of 0.02 to 30 microns dispersed throughout a matrix of polymer of alkenyl aromatic monomer and the anhydride, at least a major portion of the rubber particles containing distinct occlusions of the polymer of (a), with the further limitation that
>
> the polymer of (a) is a nonequimolar random copolymer.

The preferred ingredients are styrene, maleic anhydride, and synthetic diene rubbers, and our discussion will be in these terms, as was the Board's.

The Board's decision that the claimed invention would have been obvious in terms of 35 U.S.C. §103 was based on the combination of two references: a 1966 article by Molau and Keskkula entitled "Heterogeneous Polymer Systems IV. Mechanism of Rubber Particle Formation in Rubber-Modified Vinyl Polymers", and Baer U.S. Patent No. 2,971,939. Also discussed were Farmer U.S. Patent No. 2,275,951 and a publication by Bacon and Farmer entitled "The Interaction of Maleic Anhydride with Rubber", although the Board stated that the rejection was sustainable without relying on either of these references.

The Prior Art

The Molau/Keskkula article shows the preparation of a resin having high impact strength by dissolving synthetic diene rubber in styrene and polymerizing the styrene. This reference teaches that phase inversion is necessary to the formation of these moldable, extrudable resins. Baer prepares nonequimolar random maleic anhydride-styrene copolymers by a technique whose salient feature is adding the maleic anhydride slowly to polymerizing styrene under controlled conditions.

Farmer shows the reaction among natural rubber, styrene, and maleic anhydride, and also states that maleic anhydride reacts directly with the rubber. The Bacon and Farmer article also shows the reaction of maleic anhydride with natural rubber. These products, according to Dow's evidence and as found by the Board, do not have a dispersed rubber phase containing occlusions, and are not moldable.

Dow argues that the Board has engaged in hindsight reconstruction of the claimed invention. To support its position Dow refers to several scientific publications and other references, in addition to those cited by the PTO, and evidence submitted by declaration and deposition.

The first group of references to which Dow refers shows the reaction of maleic anhydride with natural or synthetic rubbers. These references show both intermolecular and intramolecular reactions between maleic anhydride and the various rubbers, but not a grafted rubber, which is said by Dow to characterize its product. Additional references are cited by Dow to show that maleic anhydride is much more reactive with diene-type synthetic rubbers than with natural rubber, and that the reaction with the synthetic rubbers is difficult to control and the product is unpredictable.

Another reference cited by Dow, the *Encyclopedia of Science and Technology* , states the general rule, derived from experience with acrylonitrile, that copolymers with synthetic diene rubbers have elevated glass transition temperatures; Dow advises that this is a highly undesirable property for a high-impact strength resin.

Another series of references cited by Dow shows several known techniques of reacting styrene and maleic anhydride to prepare nonequimolar copolymers, all different from the technique shown in the Baer patent.

Analysis

The Board held that the claimed product results from the application of the Baer technique to a styrene-maleic anhydride polymer system which includes synthetic diene rubber, and that it would have been obvious to do that which these inventors did if one wanted to increase the heat stability of a known high impact styrene rubber resin.

The crux of Dow's argument is that no reference shows or suggests that these references should or could be combined successfully. Indeed, the Board agreed, stating that "[i]t is not apparent from the evidence whether rubber and maleic anhydride would have been expected to react *in the process suggested by the combined disclosure of Molau and Baer* . . . ." (Emphasis in original).

Page 1531

Dow also points out, referring to the Keskkula evidence, that it was believed that these products could not be made by the mass polymerization techniques of the prior art. Dow asserts that no reference, including Baer, suggested that the Baer technique could produce the requisite phase inversion in a system containing diene rubber, and could produce a diene-rubber containing resin that could be molded and had the other desired high-impact and thermal properties.

Dow refers to the Farmer patent, cited by the examiner and the Board, which shows that the reaction of styrene, maleic anhydride, and natural rubber forms a product that is unsuitable as a molding resin. Dow argues that Farmer leads away from the Dow invention, in that Farmer obtains precisely the "runaway" reaction, and undesirable product, that Keskkula believed was characteristic of reactions involving styrene, maleic anhydride, and rubbers. Dow points to Dr. Keskkula's Report to Dow management, written in 1966 at about the time the present invention was made, pointing out the many problems in attempting to produce the three-component product that these inventors later succeeded in producing.

In response, the Commissioner argues that even though an expert polymer scientist, Dr. Keskkula, "personally may have been surprised by the invention at the time it was made, it does not necessarily follow that the invention would have been unobvious to one of ordinary skill in the art." The Commissioner suggests that one less encumbered by knowledge of the need for phase inversion, as described in the Molau/Keskkula article, might have achieved the Dow product by combining the references in the way suggested by the Commissioner. Reflecting on this theory of invention, we observe that such a person did not do so, despite the decades of experimentation with these components, and the recognition of need, as evidenced by the many references cited by both sides. *See In re Geiger* , 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed.Cir. 1987); *ACS Hospital Systems, Inc. v. Montefiore Hospital* , 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed.Cir. 1984).

The Board held that Dow's statement in the patent specification that it was known that styrene/maleic anhydride copolymers had improved heat resistance as compared with styrene rubbers, made it prima facie obvious to combine these three components. Indeed, the record shows that such combinations had previously been made, in various ways, but without producing the product here desired. That there were other attempts, and various combinations and procedures tried in the past, does not render obvious the later successful one. The PTO's reliance on Dow's "admission" of longfelt need as prima facie evidence of obviousness is contrary to logic as well as law. Recognition of need, and difficulties encountered by those skilled in the field, are classical indicia of unobviousness. *Graham v. John Deere Co* ., 383 U.S. 1, 17, 148 USPQ 459, 467 (1966); *Custom Accessories v. Jeffrey-Allan Industries* , 807 F.2d 955, 960, 1 USPQ2d 1196, 1199 (Fed.Cir. 1986). Further, a patent applicant's statement of the purpose of the work is not prior art.

The Board thus concluded that although one would not know in advance whether the Baer technique would work at all in the presence of diene rubber, or produce a moldable high-impact product, if it did

succeed it would have been obvious. The Board criticized Keskkula's evidence for not stating whether, after these inventors proposed the procedure here at issue, Keskkula would have expected the maleic anhydride to react preferentially with the diene rubber or with the styrene and to what effect on the impact properties of the product. The PTO argues that unless the prior art is shown to have led one of ordinary skill to expect the Baer technique to fail, the applicant's burden is not met. This is not the criterion. That these inventors eventually succeeded when they and others had failed does not mean that they or their colleagues must have expected each new idea to fail. Most technological advance is the fruit of methodical, persistent investigation, as is recognized in 35 U.S.C. §103 ("Patentability shall not be negatived by the manner in which the invention was made").

The consistent criterion for determination of obviousness is whether the prior art would have suggested to one of ordinary skill in the art that this process should be carried out and would have a reasonable likelihood of success, viewed in the light of the prior art. *See Burlington Industries v. Quigg* , 822 F.2d 1581, 1583, 3 USPQ2d 1436, 1438 (Fed.Cir. 1987); *In re Hedges* , 783 F.2d 1038, 1041, 228 USPQ 685, 687 (Fed.Cir. 1987); *Orthopedic Equipment Co. v. United States* , 702 F.2d 1005, 1013, 217 USPQ 193, 200 (Fed.Cir. 1983); *In re Rinehart* , 531 F.2d 1048, 1053-54, 189 USPQ 143, 148 (CCPA 1976). Both the suggestion and the expectation of success must be founded in the prior art, not in the applicant's disclosure.

In determining whether such a suggestion can fairly be gleaned from the prior art, the full field of the invention must be considered; for the person of ordinary skill is charged

Page 1532

with knowledge of the entire body of technological literature, including that which might lead away from the claimed invention. The Commissioner argues that since the PTO is no longer relying on Farmer or the Bacon and Farmer article, the applicant is creating a "straw man". It is indeed pertinent that these references teach against the present invention. Evidence that supports, rather than negates, patentability must be fairly considered.

[1] The PTO presents, in essence, an "obvious to experiment" standard for obviousness. However, selective hindsight is no more applicable to the design of experiments than it is to the combination of prior art teachings. There must be a reason or suggestion in the art for selecting the procedure used, other than the knowledge learned from the applicant's disclosure. *Interconnect Planning Corporation v. Feil* , 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed.Cir. 1985). Of the many scientific publications cited by both Dow and the PTO, none suggests that any process could be used successfully in this three-component system, to produce this product having the desired properties. The skepticism of an expert, expressed before these inventors proved him wrong, is entitled to fair evidentiary weight, *see In re Piasecki* , 745 F.2d 1468, 1475, 223 USPQ 785, 790 (Fed.Cir. 1984); *In re Zeidler* , 682 F.2d 961, 966, 215 USPQ 490, 494 (CCPA 1982), as are the five to six years of research that preceded the claimed invention. The evidence as a whole does not support the PTO's conclusion that the claimed invention would have been obvious in terms of 35 U.S.C. §103.

REVERSED

- End of Case -

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > Princeton Biochemicals Ir Beckman Coulter Inc., 75 USPQ2d 1051 (Fed. Cir. 2005)

75 USPQ2d 1051

Princeton Biochemicals Inc. v. Beckman Coulter Inc.

U.S. Court of Appeals
Federal Circuit

No. 04-1493

Decided June 9, 2005

411 F3d 1332

Headnotes

PATENTS

[1] Patentability/Validity — Obviousness — References and claims as whole (▶115.0904)

Patentability/Validity — Obviousness — Combining references (▶115.0905)

Asserted claim of patent for capillary electrophoresis device would have been obvious at time of invention in view of combination of prior art references, since evidence shows that all eight elements of asserted claim were separately known in prior art, since infringement defendant offered unrebutted expert testimony stating that both individual ideas underlying invention and combination thereof would have been obvious, and such testimony is consistent with prior art introduced at trial, since expert supplied detailed analysis of prior art and reasons why person of ordinary skill would possess knowledge and motivation to combine elements, and since nature of problem addressed by invention called for solutions existing in prior art, as well as claimed combination of closely related prior art elements.

[2] Patentability/Validity — Obviousness — Relevant prior art — Particular inventions (▶115.0903.03)

Federal district court hearing action for infringement of patent for capillary electrophoresis apparatus properly concluded that references on which it based its obviousness analysis, including those within related field of liquid chromatography, were appropriate prior art, since, during prosecution, examiner consistently rejected first six elements of asserted claim as obvious, citing references ranging from capillary electrophoresis to liquid chromatography, since district court itemized other references in chemical separations field, describing their relation to electrophoretic separation, chromatography, or both, and further established that capillary electrophoresis is closely related to types of electrophoresis described in some of cited references, since defendant's expert testified that person of ordinary skill in art would look to these related fields to solve problems in capillary electrophoresis field, and since district court examined whether references were reasonably pertinent to particular problems addressed by asserted claim, and properly determined that references addressed those problems in same manner as elements of claim.

Particular Patents

Particular patents — Chemical — Electrophoresis

5,045,172, Guzman, capillary electrophoresis apparatus, judgment of invalidity affirmed.

Case History and Disposition

Appeal from the U.S. District Court for the District of New Jersey, Cooper, J.

Action by Princeton Biochemicals Inc. against Beckman Coulter Inc. for patent infringement. Jury

found for plaintiff on issues of validity and infringement, but district court granted defendant's motion for judgment as matter of law, holding patent in suit invalid for obviousness. Plaintiff appealed. Affirmed.

Prior decision: 45 USPQ2d 1757.

Attorneys

William G. Todd and Scott J. Bornstein, of Greenberg Traurig, New York, N.Y., for plaintiff-appellant.

Joseph R. Re, Darrell L. Olson, Douglas G. Muehlhauser, and Christy G. Lea, of Knobbe, Martens, Olson & Bear, Irvine, Calif., for defendant-appellee.

Judge

Before Rader, Schall, and Gajarsa, circuit judges.

Opinion Text

Opinion By:

Rader, J.

In the United States District Court for the District of New Jersey, a jury found in favor of Plaintiff-Appellant Princeton Biochemicals, Inc. (Princeton), rejecting the claims of Defendant-Appellee Beckman Coulter, Inc. (Beckman) that Princeton's U.S. Patent No. 5,045,172 (the '172 patent) is invalid by reason of obviousness and prior invention, and finding that Beckman infringed the '172 patent. On all three questions, however, the district court found the jury's verdict unsupported by substantial evidence and granted judgment as a matter of law (JMOL) in favor

Page 1052

of Beckman. *Princeton Biochemicals, Inc. v. Beckman Coulter, Inc.*, No. 96-5541 (MLC), 2004 WL 1398227 (D.N.J. June 17, 2004). Because the district court properly concluded that substantial evidence did not support the jury's verdict of nonobviousness, this court affirms.

I.

Dr. Norberto Guzman is the inventor of the '172 patent, which he assigned to Princeton. The '172 patent claims a capillary electrophoresis device. Electrophoresis is one method available for the investigation of biological materials, and is an efficient procedure for the separation and detection of proteins and other matter. '172 patent, col. 1, ll. 16-20. Electrophoretic separation, one species of electrophoresis, relies on the differential speeds of the migration of differently charged particles in an electric field. *Id.* at col. 1, ll. 21-23. Capillary electrophoresis is one type of electrophoretic separation. *Id.* at col. 1, ll. 17-20. As the '172 patent describes,

> [I]t is generally known that a material, containing mixtures of substances to be analyzed, can be passed along a capillary tube and through a detector under the influence of an applied voltage. The applied voltage charges the substances and the charges on the substances determine their spacing and their speed of passage along the capillary tube.

Id. at col. 2, ll. 32-38. Capillary tubes, generally made of quartz, range in lengths of roughly 10 to 100 centimeters and 25-200 microns in diameter. *Id.* at col. 1, ll. 50-58. Due to the dimensions of a tube, capillary electrophoresis requires only a minute sample size to efficiently separate and identify the components of a solution.

Claim 32 of the '172 patent claims a specific capillary electrophoresis device:

> Capillary electrophoresis apparatus comprising a capillary tube of the type which can be electrically charged, said capillary tube having first and second ends,
>
> first means at said first end of said capillary tube providing a source of buffer solution and a source of a sample substance to be analyzed,
>
> second means coupled to said apparatus for applying electrical potential across said

capillary tube whereby a sample flows through said capillary tube and past said detector,

said first means includes a rotatable table carrying a plurality of sample cups and *a holder for holding an end of said capillary tube in operative relation with one of the said cups*, said cups containing either buffer solution or a sample to be analyzed, and

said capillary tube is in the form of a coil of glass tubing [secured to a support member]. *

Id. at col. 23, ll. 30-47 (emphases added). The parties stipulated that claim 32 contains eight elements, as follows:

Capillary electrophoresis apparatus comprising:

(1) a capillary tube of the type which can be electrically charged,

(2) said capillary tube having first and second ends,

(3) first means at said first end of said capillary tube providing a source of buffer solution and a source of sample substance to be analyzed,

(4) second means coupled to said apparatus for applying electrical potential across said capillary tube whereby a sample flows through said capillary tube and past said detector,

(5) said first means includes a rotatable table carrying a plurality of sample cups and

(6) a holder for holding an end of said capillary tube in operative relation with one of the said cups, said cups containing either buffer solution or a sample to be analyzed, and

(7) said capillary tube is in the form of a coil of glass tubing

(8) secured to a support member.

Id.

Beckman manufactures and sells the P/ACE 2000 and 5000 Series capillary electrophoresis devices ("the accused devices" or

Page 1053

"the P/ACE devices"). Beckman contends a prototype device, named OTEP II, contained all the elements recited in claim 32. Princeton does not contest that Beckman made OTEP II by February 1, 1987. That date, therefore, is the relevant reduction-to-practice date for the P/ACE devices. Beckman began selling P/ACE devices as early as 1993.

Guzman filed the application for the '172 patent on November 14, 1988. Thus, the critical date for evaluating 35 U.S.C. §102(b) prior art references is November 14, 1987. Several references, published before November 14, 1987, discussed the electrophoretic concepts embodied in claim 32 of the '172 patent. Two particular references stand out. The first, an article by Honda dated September 1987, describes ways to introduce automatically different samples into a capillary electrophoresis device. Susumu Honda, et. al., "Evaluation of an Automatic Siphonic Sampler for Capillary Zone Electrophoresis," *Int'l J. on Chromatography, Electrophoresis and Related Methods*. The second, a Ph.D. thesis by Lukacs, was published in 1983 by a graduate student of Dr. James W. Jorgenson, an expert who testified on behalf of Beckman. The Lukacs thesis discloses the coiling of capillary tubes during electrophoretic work. Coiling a capillary tube lengthens the tubing without increasing the size of the electrophoretic device. A longer tube provides better separation and identification of analytes.

On November 21, 1996, Princeton filed suit, alleging that the P/ACE devices infringed claim 32 of the ' 172 patent. Beckman denied infringement and sought a declaration of invalidity on grounds of obviousness and prior invention. Following a grant of summary judgment of noninfringement, Princeton appealed. In an unpublished opinion, this court reversed, holding that the district court had improperly construed the sixth element in claim 32. *Princeton Biochemicals, Inc. v. Beckman Instruments, Inc.*, 1999 WL 641233, at *6 (Fed. Cir. 1999) ("The proper interpretation of the holder limitation is that 'in operative relation' encompasses both vertical movement of the holder as well as vertical movement of the sample cups and the table.").

On remand, the district court conducted a nine-day trial followed by motions for JMOL from both parties. The district court reserved judgment until after the jury verdict. The jury decided in favor of

Princeton on all issues. Specifically, the jury found that Princeton proved by a preponderance of the evidence that Beckman's devices infringed claim 32 of the '172 patent; that Beckman did not prove by clear and convincing evidence that claim 32 of the patent was invalid for obviousness; and finally, that Beckman did not prove "by clear and convincing evidence that claim 32 is invalid because the invention described in that claim was made by Beckman before it was made by Princeton." Beckman timely renewed its JMOL motion and moved alternatively for a new trial.

In due course, the district court issued a carefully composed, 194-page opinion that set aside the jury's verdict and found all counts in favor of Beckman. *Princeton Biochemicals, Inc.*, 2004 WL 1398227. The district court also granted Beckman's motion for a new trial. *Id.* at *91. Princeton timely appealed to this court. This court has jurisdiction under 28 U.S.C. §1295(a)(1).

II.

"The grant or denial of a motion for judgment as a matter of law is a procedural issue not unique to patent law, reviewed under the law of the regional circuit in which the appeal from the district court would usually lie." *Summit Tech., Inc. v. Nidek Co.*, 363 F.3d 1219, 1223 [70 USPQ2d 1276] (Fed. Cir. 2004). Under the law of the Third Circuit, review of a district court's ruling on JMOL is plenary. *Shellenberger v. Summit Bancorp, Inc.*, 318 F.3d 183, 186 (3rd Cir. 2003). The party requesting the JMOL must show that substantial evidence did not support the jury's findings, where substantial evidence is "such relevant evidence from the record taken as a whole as might be accepted by a reasonable mind as adequate to support the finding under review." *Tex. Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1563 [39 USPQ2d 1492] (Fed. Cir. 1996). This court must also consider all the evidence before the jury and draw all reasonable inferences in favor of the prevailing party on that issue, i.e., the non-movant. *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1479 [44 USPQ2d 1181] (Fed. Cir. 1997). Regarding the obviousness issue in this case, this court must determine whether the jury had substantial evidence upon which to conclude that Beckman

Page 1054

met its burden of showing invalidity by clear and convincing evidence.

This court also reviews the legal standards that the jury applied in reaching its verdict to determine whether they were correct as a matter of law. *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 975 [34 USPQ2d 1321] (Fed. Cir. 1995) (*en banc*), *aff'd*, 517 U.S. 370, 134 L. Ed. 2d 577, 116 S. Ct. 1384 [38 USPQ2d 1461] (1996). When reviewing a jury's verdict on obviousness the court reviews the "conclusions on obviousness, a question of law, without deference, and the underlying findings of fact, whether explicit or implicit within the verdict, for substantial evidence." *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 [61 USPQ2d 1193] (Fed. Cir. 2001). Specifically, the jury is presumed to have "resolved the underlying factual disputes in favor of the verdict winner and [this court leaves] those presumed findings undisturbed if they are supported by substantial evidence". *Jurgens v. McKasy*, 927 F.2d 1552, 1557 [18 USPQ2d 1031] (Fed. Cir. 1991).

III.

Section 103 of title 35 of the United States Code states:

> A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

35 U.S.C. §103(a) (2000). The legal conclusion, that a claim is obvious within §103(a), depends on at least four underlying factual issues: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) evaluation of any relevant secondary considerations. *See Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 [148 USPQ 459] (1966). Analyzing the record support for those factors for Beckman's Rule 50(b) motion, the trial court concluded that claim 32 was obvious. Thus, the court granted Beckman's motion for JMOL, set aside the jury verdict rejecting the obviousness challenge, and entered judgment invalidating claim 32.

There is no dispute that the references introduced at trial disclosed every element in claim 32. Guzman admitted this in his testimony at trial. Thus, aside from the relevance of the asserted

references, the only disputed issue at trial, and asserted on appeal, was whether there was motivation to combine the elements already present in the prior art. As this court outlined in *Ruiz v. A.B. Chance Co.*, 357 F.3d 1270, 1275 [69 USPQ2d 1686] (Fed. Cir. 2004), in making the assessment of differences between the prior art and the claimed subject matter, section 103 specifically requires consideration of the claimed invention "as a whole." Inventions typically are new combinations of existing principles or features. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 [218 USPQ 865] (Fed. Cir. 1983) (noting that "virtually all [inventions] are combinations of old elements"). The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. *Ruiz*, 357 F.3d at 1275. Without this important requirement, an obviousness assessment might successfully break an invention into its component parts, then find a prior art reference corresponding to each component. *Id.* This line of reasoning would import hindsight into the obviousness determination by using the invention as a roadmap to find its prior art components. Further, this improper method would discount the value of combining various existing features or principles in a new way to achieve a new result - often the essence of invention. *Id.*

Contrary to this reasoning, section 103 requires assessment of the invention as a whole. *Id.* This "as a whole" assessment of the invention requires a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would have selected the various elements from the prior art and combined them in the claimed manner. *Id.* In other words, section 103 requires some suggestion or motivation, before the invention itself, to make the new combination. *See In re Rouffet*, 149 F.3d 1350, 1355-56 [47 USPQ2d 1453] (Fed. Cir. 1998).

[1] In setting aside the jury's verdict and holding claim 32 obvious, the district court systematically and vigilantly considered the relevant prior art references and testimony of

Page 1055

both parties. The Honda article relates to claim 32's first six elements and describes an automated capillary electrophoresis device with a rotatable table carrying a plurality of sample cups. Princeton does not contest that the Honda article discloses elements one through six. Therefore, at the time of Princeton's claim 32 invention, the prior art had disclosed elements one through six.

With respect to the seventh element, the district court found that the Lukacs thesis disclosed the construction and use of a coiled glass capillary in a capillary electrophoresis apparatus. *Princeton Biochemicals, Inc.*, 2004 WL 1398227, at *40. Additionally, Dr. Jorgenson testified about Ms. Lukacs's work with coiled capillaries based on his own observations in the laboratory with Ms. Lukacs. He noted that they coiled glass capillaries that were two to three meters and longer. *Id.* at *24. In light of the Lukacs thesis, Dr. Guzman conceded at trial that he was not the first to coil a capillary in an electrophoresis device. *Id.* at *40. Therefore, at the time of Princeton's claim 32 invention, element 7 was also known in the prior art.

Element 8 of claim 32 recites the requirement that the capillary tube of claim 32, in the form of glass tubing, must be "secured to a support member." At trial, Dr. Guzman testified that he did not invent "securing capillary tubes or any portion thereof to support members" and did not deny that this element was "old" or that it did not "add" anything new to the claim. From this, the district court correctly concluded that element 8 was known in the prior art. *Id.* at *40. Furthermore, in its brief to this court, Princeton conceded that elements one through eight were separately known in the prior art.

As discussed, simply identifying all of the elements in a claim in the prior art does not render a claim obvious. *Ruiz*, 357 F.3d at 1275. Instead section 103 requires some suggestion or motivation in the prior art to make the new combination. *Rouffet*, 149 F.3d at 1355-56. A suggestion or motivation to modify prior art teachings may appear in the content of the public prior art, in the nature of the problem addressed by the invention, or even in the knowledge of one of ordinary skill in the art. *SIBIA Neurosciences, Inc. v. Cadus Pharm. Corp.*, 225 F.3d 1349, 1356 [55 USPQ2d 1927] (Fed. Cir. 2000).

Dr. Jorgenson testified that the motivation to combine these references was found in the knowledge of those skilled in the art at the time of Guzman's invention. *See SIBIA Neurosciences, Inc.*, 225 F.3d at 1356 (stating that motivation, suggestion or reason to combine items of prior art may come from the knowledge of one of ordinary skill in the art). As Jorgenson explained:

> [T]he combination is obvious. Every one of the individual ideas is obvious. And the combination is absolutely obvious. Everybody in all of the related fields in all of the related

> technologies is doing those kinds of things .... The entire package taken together is obvious.

Id. Princeton offered no evidence to rebut Dr. Jorgenson's testimony.

Dr. Jorgenson's testimony on motivation to combine is unrebutted. Moreover, it is consistent with the prior art introduced at trial. The only additions to the Honda prior art in this invention were coiling the capillaries (Lukacs prior art) and supporting the coils (concededly prior art). Both of those simple additions appear in other prior art references. Thus, Dr. Jorgenson testified, without any rebutting evidence in the record, that the suggestion to coil and secure the capillaries in the Honda device was within the knowledge of one of skill in the art. In *In re Lee*, this court expressed skepticism about invoking the knowledge of a skilled artisan to supply the motivation to combine on a scanty record. 277 F.3d 1338, 1343-44 [61 USPQ2d 1430] (Fed. Cir. 2002) ("This factual question of motivation ... could not be resolved on subjective belief and unknown authority."). Dr. Jorgenson supplied detailed analysis of the prior art and the reasons that one of ordinary skill would possess knowledge and motivation to combine these simple elements.

In addition, the nature of the problem supplies a motivation to combine these prior art references. The district court provided a detailed analysis of the nature of the problem solved by the invention. *Princeton Biochemicals, Inc.*, 2004 WL 1398227, at *37-40. The problem was lengthening and securing the capillaries on the Honda automatic device to produce better separation. *Id.* at *38. The prior art Lukacs thesis stated that lengthening was precisely the reason for coiling. *Id.* at *39. With regard to securing, Dr. Osborne, a Beckman

witness, testified about the problem of a capillary electrophoresis device whose capillary swayed during use and affected the separation result. *Id.* Dr. Osborne observed: "[W]e did not want the capillary to move during the separation." *Id.* In other words, the nature of the problem called for exactly the solutions in the prior art. Moreover the nature of the problem, as noted again in Dr. Jorgenson's testimony, called for the combination. Dr. Jorgenson observed that the problem called for coiled electrophoresis tubes, including capillary tubes, secured in place in a variety of ways. *Id.* He also testified that one of ordinary skill in the art at the time of the invention would know to coil a capillary to save space. *Id.* Regarding the securing of a capillary tube to a support member, Dr. Jorgenson also testified that it would be obvious to one of ordinary skill in the art to do so, as "you don't want a coil floating around without some kind of support." *Id.* Thus, the nature of the problem also supplies a motivation to make this combination of closely related prior art elements.

The district court also properly found that the references for this obviousness analysis were proper prior art. A reference is appropriate prior art if within the field of the inventor's endeavor. *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 449 [230 USPQ 416] (Fed. Cir. 1986). Alternatively, a reference qualifies as prior art if "reasonably pertinent to the particular problem with which the inventor was involved." *Id.* "A reference is reasonably pertinent if, even though it may be in a different field of endeavor, it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his problem." *In re GPAC Inc.*, 57 F.3d 1573, 1578 [35 USPQ2d 1116] (Fed. Cir. 1995) (quotations and citations omitted). If a reference's disclosure relates to the same problem as the claimed invention, "that fact supports use of that reference in an obviousness rejection." *In re Clay*, 966 F.2d 656, 659 [23 USPQ2d 1058] (Fed. Cir. 1992).

[2] In this case, all the references for obviousness constitute analogous art, even though some of the references fall within the related field of liquid chromatography. Throughout the prosecution history of the '172 patent, the examiner consistently rejected elements one through six of claim 32 as obvious, citing references ranging from capillary electrophoresis to liquid chromatography – a related means of separating analytes. The examiner stated on the record: "[L]iquid chromatography and capillary electrophoresis are closely related techniques." The district court also itemized other references in the chemical separations field, describing the relation to electrophoretic separation or chromatography or both. *Princeton Biochemicals, Inc.*, 2004 WL 1398227, at *36-37. The district court further established that capillary electrophoresis is closely related to the types of electrophoreses described in some of the references. *Id.* at *37. Finally, Dr. Jorgenson offered expert testimony that one of ordinary skill in the art would look to these related fields to solve problems in the field of capillary electrophoresis. *Id.* at *37.

The district court also examined whether the prior art references were reasonably pertinent to the particular problems with which the invention of claim 32 was involved. *Id.* at *37-39. In defining such problems, the district court looked to Dr. Guzman's own testimony that the electrophoretic device needed to be compact and immobile. *Id.* at *38. As already noted, the district court properly assessed that the prior art references addressed those same problems in the same way. *Id.* at *39. In sum, the district court used proper prior art references in its correct obviousness analysis.

Viewing the evidence as a whole and in a light most favorable to Princeton, this court agrees with the district court that there was not substantial evidence to support the jury verdict. Because claim 32 is invalid for obviousness, this court need not reach the issues of prior invention and infringement.

COSTS

Each party shall bear its own costs.

AFFIRMED

* The words "secured to a support member" are not pressent in the final, published version of the '172 patent. The parties stipulated at trial that this was a printing error only. Those words appear in claim 32 as issued.

- End of Case -

ISSN 1526-8535

47 USPQ2d 1453
In re Rouffet
U.S. Court of Appeals Federal Circuit

No. 97-1492

Decided July 15, 1998

149 F3d 1350

Headnotes

PATENTS

[1] Patentability/Validity -- Obviousness -- Combining references (► 115.0905)

Claimed low orbit satellite communications system for mobile terminals, which addresses problem of minimizing "handover" of receiver from beam footprint of one transmitting satellite to that of another through use of multiple fan-shaped beams, is not prima facie obvious over combination of three prior art references, since critical reference that teaches use of fan-shaped beam to transmit from ground station to orbiting satellites does not specifically address handover minimization, and to extent it addresses handover problem at all, does so with orbit selection rather than beam shape, and since there is no reason one of ordinary skill in art, seeking to minimize handovers due to satellite motion, would have been motivated to combine this reference with remaining references in manner that would render claimed invention obvious.

[2] Patentability/Validity -- Obviousness -- Person of ordinary skill in art (► 115.0902)

Patentability/Validity -- Obviousness -- Combining references (► 115.0905)

Three possible sources for motivation to combine prior art references in manner that would render claimed invention obvious are nature of problem to be solved, teachings of prior art, and knowledge of persons of ordinary skill in art; high level of skill in field of art cannot be relied upon to provide necessary motivation absent explanation of what specific understanding or technical principle, within knowledge one of ordinary skill in art, would have suggested combination, since, if such rote invocation could suffice to supply motivation to combine, more sophisticated scientific fields would rarely, if ever, experience patentable technical advance.

Page 1454

[3] Patentability/Validity -- Obviousness -- Person of ordinary skill in art (► 115.0902)

Patentability/Validity -- Obviousness -- Combining references (► 115.0905)

Claimed low orbit satellite communications system for mobile terminals is not prima facie obvious over combination of two prior art references, even though person possessing high level of skill characteristic of this field would know to account for differences between claimed invention and prior art combination, since high level of skill in art, without more, cannot supply required motivation to combine references, and does not overcome absence of any actual suggestion to combine; obviousness rejection will not be upheld, even where skill in art is high, absent specific identification of principle, known to one of ordinary skill, that suggests claimed combination.

Case History and Disposition

Page 1454

Appeal from the U.S. Patent and Trademark Office, Board of Patent Appeals and Interferences.

Patent application of Denis Rouffet, Yannick Tanguy, and Frederic Berthault, serial no. 07/888,791, filed May 27, 1992. From decision upholding examiner's final rejection of application as obvious under 35 USC 103(a), applicants appeal. Reversed.

Attorneys

Richard C. Turner and Grant K. Rowan, of Sughrue, Mion, Zinn, Macpeak & Seas, Washington, D.C., for appellants.

David J. Ball Jr., associate solicitor, Nancy J. Linck, solicitor, Albin F. Drost, deputy solicitor, Craig R. Kaufman, associate solicitor, and Scott A. Chambers, associate solicitor, U.S. Patent and Trademark Office, Arlington, Va., for appellee.

Judge

Before Plager, circuit, judge, Archer, senior circuit judge, and Rader, circuit judge.

Opinion Text

Opinion By:

Rader, J.

Denis Rouffet, Yannick Tanguy, and Frederic Berthault (collectively, Rouffet) submitted application 07/888,791 (the application) on May 27, 1992. The Board of Patent Appeals and Interferences (the Board) *affirmed* final rejection of the application as obvious under 35 U.S.C. Section 103(a). *See Ex parte Rouffet* , No. 96-1553 (Bd. Pat. App. & Int. Apr. 16, 1997). Because the Board reversibly erred in identifying a motivation to combine the references, this court reverses.

I.

Satellites in a geosynchronous or geostationary orbit remain over the same point on the Earth's surface. Their constant position above the Earth's surface facilitates communications. These satellites project a number of beams to the Earth. Each beam transmits to its area of coverage, or footprint, on the Earth's surface. In order to provide complete coverage, adjacent footprints overlap slightly and therefore must use different frequencies to avoid interference. However, two or more non-overlapping footprints can use the same set of frequencies in order to use efficiently the limited radio spectrum. Figure 1 from the application shows the coverage of a portion of the Earth's surface provided by multiple cone shaped beams:

Frequency reuse techniques, however, have a limited ability to compensate for congestion in geostationary orbits. To alleviate the orbit congestion problem, new telecommunications systems use a network of satellites in low Earth orbit. When viewed from a fixed point on the Earth's surface, such satellites do not remain stationary but move overhead. A satellite's motion as it transmits a plurality of cone-shaped beams creates a new problem. The satellite's movement causes a receiver on the Earth's surface to move from the footprint of one beam into a second beam transmitted by the same satellite. Eventually, the satellite's motion causes the receiver to move from the footprint of a beam transmitted by one satellite into the footprint of a beam transmitted by a second satellite. Each switch from one footprint to another creates a "handover" event analogous to that which occurs when a traditional cellular phone travels from one cell to another. Handovers are undesirable because

Page 1455

they can cause interruptions in signal transmission and reception.

Rouffet's application discloses technology to reduce the number of handovers between beams transmitted by the same satellite. In particular, Rouffet eliminates handovers caused solely by the satellite's motion. To accomplish this goal, Rouffet changes the shape of the beam transmitted by the satellite's antenna. Rouffet's satellites transmit fan-shaped beams. A fan beam has an elliptical footprint. Rouffet aligns the long axis of his beams parallel to the direction of the satellite's motion across the Earth's surface. By elongating the beam's footprint in the direction of satellite travel, Rouffet's invention ensures that a fixed point on the Earth's surface likely will remain within a single

footprint until it is necessary to switch to another satellite. Because Rouffet's invention does not address handovers caused by the motion of the receiver across the Earth's surface, his arrangement reduces, but does not eliminate, handovers. Figure 3 from the application shows the footprints 12 from six beams aligned in the direction of satellite motion 15:

The application contains ten claims that stand or fall as a group. Claim 1 is representative:

> A low orbit satellite communications system for mobile terminals, wherein the communications antenna system of each satellite provides isoflux coverage made up of a plurality of fan beams that are elongate in the travel direction of the satellite.

The examiner initially rejected Rouffet's claims as unpatentable over U.S. Pat. No. 5,199,672 (King) in view of U.S. Pat. No. 4,872,015 (Rosen) and a conference report entitled "A Novel Non-Geostationary Satellite Communications System," *Conference Record* , International Conference on Communications, 1981 (Ruddy). On appeal to the Board, the examiner added an alternative ground for rejection, holding that the claims were obvious over U.S. Pat. No. 5,394,561 (Freeburg) in view of U.S. Pat. No. 5,170,485 (Levine).

On April 16, 1997, the Board issued its decision. Because Rouffet had specified that the claims would stand or fall as a group based on the patentability of claim 1, the Board limited its opinion to that claim. The Board unanimously determined that the examiner had properly rejected claim 1 as obvious over King in view of Rosen and Ruddy. The Board, on a split vote, also *affirmed* the rejection over Freeburg in view of Levine.

II

To reject claims in an application under section 103, an examiner must show an unrebutted *prima facie* case of obviousness. *See In re Deuel* , 51 F.3d 1552, 1557, 34 USPQ2d 1210, 1214 (Fed.Cir. 1995). In the absence of a proper *prima facie* case of obviousness, an applicant who complies with the other statutory requirements is entitled to a patent. *See In re Oetiker* , 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed.Cir. 1992). On appeal to the Board, an applicant can overcome a rejection by showing insufficient evidence of *prima facie* obviousness or by rebutting the *prima facie* case with evidence of secondary indicia of nonobviousness. *See id.*

While this court reviews the Board's determination in light of the entire record, an applicant may specifically challenge an obviousness rejection by showing that the Board reached an incorrect conclusion of obviousness or that the Board based its obviousness determination on incorrect factual predicates. This court reviews the ultimate determination of obviousness as a question of law. *See In re Lueders* , 111 F.3d 1569, 1571, 42 USPQ2d 1481, 1482 (Fed.Cir. 1997). The factual predicates underlying an obviousness determination include the scope and content of the prior art, the differences between the prior art and the claimed invention, and the level of ordinary skill in the art. *See Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH* , 139 F.3d 877, 881, 45 USPQ2d 1977, 1981 (Fed.Cir. 1998). This court reviews the Board's factual findings for clear error. *See In re Zurko* , 142 F.3d 1447, 1449, 46 USPQ2d 1691, 1693 (Fed.Cir. 1998) (in banc); *Leuders* , 111 F.3d at 1571-72. " 'A finding is clearly erroneous when, although there is evidence to support it, the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed.' " *In re Graves* , 69 F.3d 1147, 1151, 36 USPQ2d

Page 1456

1697, 1700 (Fed.Cir. 1995) (quoting *United States v. United States Gypsum Co.* , 333 U.S. 364, 395 [76 USPQ 430] (1948)).

The secondary considerations are also essential components of the obviousness determination. *See In re Emert* , 124 F.3d 1458, 1462, 44 USPQ2d 1149, 1153 (Fed.Cir. 1997) ("Without Emert providing rebuttal evidence, this *prima facie* case of obviousness must stand."). This objective evidence of nonobviousness includes copying, long felt but unsolved need, failure of others, *see Graham v. John Deere Co.* , 383 U.S. 1, 17-18 [148 USPQ 459] (1966), commercial success, *see In re Huang* , 100 F.3d 135, 139-40, 40 USPQ2d 1685, 1689-90 (Fed.Cir. 1996), unexpected results created by the claimed invention, unexpected properties of the claimed invention, *see In re Mayne* , 104 F.3d 1339, 1342, 41 USPQ2d 1451, 1454 (Fed.Cir. 1997); *In re Woodruff* , 919 F.2d 1575, 1578, 16 USPQ2d 1934, 1936-37 (Fed.Cir. 1990), licenses showing industry respect for the invention, *see Arkie Lures, Inc. v. Gene Larew Tackle, Inc.* , 119 F.3d 953, 957, 43 USPQ2d 1294, 1297 (Fed.Cir. 1997); *Pentec, Inc. v. Graphic Controls Corp.* , 776 F.2d 309, 316, 227 USPQ 766, 771 (Fed.Cir. 1985), and

skepticism of skilled artisans before the invention, *see In re Dow Chem. Co.* , 837 F.2d 469, 473, 5 USPQ2d 1529, 1532 (Fed.Cir. 1988). The Board must consider all of the applicant's evidence. *See Oetiker* , 977 F.2d at 1445 ("An observation by the Board that the examiner made a *prima facie* case is not improper, as long as the ultimate determination of patentability is made on the entire record."); *In re Piasecki* , 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed.Cir. 1984). The court reviews factual conclusions drawn from this evidence for clear error. Whether the evidence presented suffices to rebut the *prima facie* case is part of the ultimate conclusion of obviousness and is therefore a question of law.

When a rejection depends on a combination of prior art references, there must be some teaching, suggestion, or motivation to combine the references. *See In re Geiger* , 815 F.2d 686, 688, 2 USPQ2d 1276, 1278 (Fed.Cir. 1987). Although the suggestion to combine references may flow from the nature of the problem, *see Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc.* , 75 F.3d 1568, 1573, 37 USPQ2d 1626, 1630 (Fed.Cir. 1996), the suggestion more often comes from the teachings of the pertinent references, *see In re Sernaker* , 702 F.2d 989, 994, 217 USPQ 1, 5 (Fed.Cir. 1983), or from the ordinary knowledge of those skilled in the art that certain references are of special importance in a particular field, *see Pro-Mold* , 75 F.3d at 1573 (citing *Ashland Oil, Inc. v. Delta Resins & Refractories, Inc.* , 776 F.2d 281, 297 n.24, 227 USPQ 657, 667 n.24 (Fed.Cir. 1985)). Therefore, " [w]hen determining the patentability of a claimed invention which combines two known elements, "the question is whether there is something in the prior art as a whole to suggest the desirability, and thus the obviousness, of making the combination.' " *See In re Beattie* , 974 F.2d 1309, 1311-12, 24 USPQ2d 1040, 1042 (Fed.Cir. 1992) (quoting *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.* , 730 F.2d 1452, 1462, 221 USPQ 481, 488 (Fed.Cir. 1984)).

III

The parties agree that the five references asserted by the examiner are in the same field of endeavor as the invention. The parties also agree that the pertinent level of skill in the art -- design of satellite communications systems -- is high. On appeal, Rouffet asserts that the examiner and the Board erred by improperly combining references to render the claimed invention obvious.

The Combination of King, Rosen, and Ruddy

The Board first *affirmed* the rejection of Rouffet's claims over a combination of King, Rosen, and Ruddy. King discloses a system for launching a plurality of satellites into low Earth orbits from a single launch vehicle. Rosen teaches a geostationary satellite that uses a plurality of fan beams with their long axes oriented in an east-west direction to communicate with mobile and fixed terminals on the Earth.

The final, and most important, reference in this combination is Ruddy. Ruddy describes a television broadcast system that uses a series of satellites to retransmit signals sent from a ground station over a wide area. Rather than using a geostationary orbit, Ruddy teaches the use of a series of satellites in Molniya orbits. A satellite in a Molniya orbit always follows the same path through the sky when viewed from a fixed point on the ground. Viewed from the Earth, the orbital path includes a narrow, elliptical apogee loop. In order to transmit to these moving satellites from a ground station, Ruddy uses a fan beam with a long axis aligned with the long axis of the orbit's apogee loop. This alignment places the entire apogee loop within the footprint of the beam and eliminates the need for the ground station's antenna to track the satellite's motion around the apogee loop. Ruddy further teaches orbit parameters

Page 1457

and spacing of multiple satellites to ensure that a satellite is always in the loop to receive and rebroadcast signals from the Earth station.

King and Rosen together teach the use of a network of satellites in low Earth orbit. Thus, Ruddy becomes the piece of the prior art mosaic that shows, in the reading of the Board, the use of "a plurality of fan beams that are elongate in the travel direction of the satellite." Ruddy, however, is different from the claimed invention in several respects. Specifically, the application claims the projection of multiple elliptical fan-shaped footprints from the satellite to the ground. *See* Claim 1, *supra* , *see also* Application at 6, lines 9-11 ("In addition, in this system, the geometrical shape of the beams 12 is changed: instead of being circular they are now elongate ellipses."). The application's written description further teaches that the invention's fan-shaped satellite beams will minimize

handovers. *See id.* at lines 11-16 ("This considerably increases call durations between handovers.").

In contrast, Ruddy teaches that a ground station may use a single fan-shaped beam to transmit to a satellite in a unique Molniya orbit. The ground station transmits a beam into which a series of satellites in Molniya orbits will successively enter. At least two differences are evident: the application teaches projection of multiple beams from a satellite to the Earth, while Ruddy teaches projection of a single beam from the Earth to satellites. Moreover to the extent Ruddy contains a teaching about handovers, its teachings focus on use of the unique Molniya orbit to ensure that a satellite always falls within the beam transmitted by the ground station.

These differences suggest some difficulty in showing a *prima facie* case of obviousness. The Board, however, specifically found that artisans of ordinary skill in this field of art would know to shift the frame of reference from a ground station following a satellite to a satellite transmitting to the ground. According proper deference to the Board's finding of a lofty skill level for ordinary artisans in this field, this court discerns no clear error in the Board's conclusion that these differences would not preclude a finding of obviousness. While Ruddy does not expressly teach alignment of the fan beam with the apparent direction of the satellite's motion, this court perceives no clear error in the Board's determination that Ruddy would suggest such an alignment to one of skill in this art. Therefore, the Board did not err in finding that the combination of King, Rosen, and Ruddy contains all of the elements claimed in Rouffet's application.

[1] However, the Board reversibly erred in determining that one of skill in the art would have been motivated to combine these references in a manner that rendered the claimed invention obvious. Indeed, the Board did not identify any motivation to choose these references for combination. Ruddy does not specifically address handover minimization. To the extent that Ruddy at all addresses handovers due to satellite motion, it addresses this subject through the selection of orbital parameters. Ruddy does not teach the choice of a particular shape and alignment of the beam projected by the satellite. Thus Ruddy addresses the handover problem with an orbit selection, not a beam shape. The Board provides no reasons that one of ordinary skill in this art, seeking to minimize handovers due to satellite motion, would combine Ruddy with Rosen and King in a manner that would render the claimed invention obvious.

Obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. *See* 35 U.S.C. Section 103(a). This legal construct is akin to the "reasonable person" used as a reference in negligence determinations. The legal construct also presumes that all prior art references in the field of the invention are available to this hypothetical skilled artisan. *See In re Carlson* , 983 F.2d 1032, 1038, 25 USPQ2d 1207, 1211 (Fed.Cir. 1993).

As this court has stated, "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co.* , 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed.Cir. 1983); *see also Richdel, Inc. v. Sunspool Corp.* , 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed.Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements."). Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint for piecing together elements in the prior art to defeat the patentability of the claimed invention. Such an approach would be "an illogical and inappropriate process by which to determine patentability." *Sensonics, Inc. v. Aerosonic Corp.* , 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed.Cir. 1996).

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to

Page 1458

show a motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventor and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

[2] This court has identified three possible sources for a motivation to combine references: the nature of the problem to be solved, the teachings of the prior art, and the knowledge of persons of ordinary skill in the art. In this case, the Board relied upon none of these. Rather, just as it relied on

the high level of skill in the art to overcome the differences between the claimed invention and the selected elements in the references, it relied upon the high level of skill in the art to provide the necessary motivation. The Board did not, however, explain what specific understanding or technological principle within the knowledge of one of ordinary skill in the art would have suggested the combination. Instead, the Board merely invoked the high level of skill in the art. If such a rote invocation could suffice to supply a motivation to combine, the more sophisticated scientific fields would rarely, if ever, experience a patentable technical advance. Instead, in complex scientific fields, the Board could routinely identify the prior art elements in an application, invoke the lofty level of skill, and rest its case for rejection. To counter this potential weakness in the obviousness construct, the suggestion to combine requirement stands as a critical safeguard against hindsight analysis and rote application of the legal test for obviousness.

Because the Board did not explain the specific understanding or principle within the knowledge of a skilled artisan that would motivate one with no knowledge of Rouffet's invention to make the combination, this court infers that the examiner selected these references with the assistance of hindsight. This court forbids the use of hindsight in the selection of references that comprise the case of obviousness. *See In re Gorman* , 933 F.2d 982, 986, 18 USPQ2d 1885, 1888 (Fed.Cir. 1991). Lacking a motivation to combine references, the Board did not show a proper *prima facie* case of obviousness. This court reverses the rejection over the combination of King, Rosen, and Ruddy.

The Combination of Freeburg and Levine

Freeburg teaches a cellular radiotelephone system based on a constellation of low Earth orbit satellites that use conical beams to transmit from the satellite to both fixed and mobile Earth stations. Levine teaches an Earth-based cellular radio system that uses fan beams broadcast from antenna towers. Levine's elliptical footprints are aligned with the road grid. To increase the capacity of traditional ground-based systems through frequency reuse techniques, Levine teaches the use of antennas that broadcast signals with smaller footprints than the prior art system. Thus, Levine actually increases the number of overlap regions between cells and, hence, the number of potential handovers. Figure 1 of the Levine patent illustrates its alignment of beam footprints:

As a mobile unit (e.g., a driver using a car phone) moves through a succession of overlapping zones, Levine uses selection algorithms to determine which of the cells is aligned with the travel direction of the mobile unit. These algorithms then select this cell for use while continually monitoring intersecting cells in the event that the mobile unit changes direction.

Once again, this court notes significant differences between the teachings of the application and the Levine-Freeburg combination. The critical Levine reference again involves a beam from an Earth station without any reference to the "travel direction of [a] satellite." Moreover, Levine actually multiplies the number of potential handovers and then uses software to sort out the necessary handovers from the unnecessary. However, the Board explains the reasons that one possessing the lofty skills characteristic of this field would know to account for the differences between the claimed invention and the prior art combination. This court discerns no clear error in that reliance on the considerable skills in this field.

Page 1459

[3] This court does, however, discern reversible error in the Board's identification of a motivation to combine Levine and Freeburg. In determining that one of skill in the art would have had motivation to combine Levine and Freeburg, the Board noted that " [t]he level of skill in the art is very high." As noted before, this observation alone cannot supply the required suggestion to combine these references. The Board posits that the high level of skill in the art overcomes the absence of any actual suggestion that one could select part of the teachings of Levine for combination with the satellite system disclosed by Freeburg.

As noted above, the suggestion to combine requirement is a safeguard against the use of hindsight combinations to negate patentability. While the skill level is a component of the inquiry for a suggestion to combine, a lofty level of skill alone does not suffice to supply a motivation to combine. Otherwise a high level of ordinary skill in an art field would almost always preclude patentable inventions. As this court has often noted, invention itself is the process of combining prior art in a nonobvious manner. *See, e.g.* , *Richdel* , 714 F.2d at 1579; *Environmental Designs* , 713 F.2d at 698. Therefore, even when the level of skill in the art is high, the Board must identify specifically the principle, known to one of ordinary skill, that suggests the claimed combination. *Cf. Gechter v.*

Davidson , 116 F.3d 1454, 43 USPQ2d 1030 (Fed.Cir. 1997) (explaining that the Board's opinion must describe the basis for its decision). In other words, the Board must explain the reasons one of ordinary skill in the art would have been motivated to select the references and to combine them to render the claimed invention obvious.

The Board's naked invocation of skill in the art to supply a suggestion to combine the references cited in this case is therefore clearly erroneous. Absent any proper motivation to combine part of Levine's teachings with Freeburg's satellite system, the rejection of Rouffet's claim over these references was improper and is *reversed*.

IV

The Board reversibly erred in determining that there was a motivation to combine either the teachings of King, Rosen, and Ruddy or of Freeburg and Levine in a manner that would render the claimed invention obvious. Because this predicate was missing in each case, the Board did not properly show that these references render the claimed invention obvious. Therefore this court reverses the Board's decision upholding the rejection of Rouffet's claims. In light of this disposition, Rouffet's pending motion to remand the case to the Board for further consideration is denied as moot.

COSTS

Each party shall bear its own costs.

REVERSED .

- End of Case -

ISSN 1526-8535

Source: USPQ, 2d Series (1986 - Present) > U.S. Court of Appeals, Federal Circuit > Ruiz v. A.B. Chance Co., 1686 (Fed. Cir. 2004)

69 USPQ2d 1686
Ruiz v. A.B. Chance Co.
U.S. Court of Appeals
Federal Circuit

No. 03-1333

Decided January 29, 2004

357 F3d 1270

Headnotes

PATENTS

[1] Patentability/Validity — Obviousness — Combining references (▶115.0905)

Obviousness analysis requires court to assess invention as whole to determine whether there was suggestion or motivation to combine prior art references, without engaging in improper "hindsight" determination, but finding of obviousness does not require existence of express, written motivation to combine in

Page 1687

prior art, since motivation to combine may be found in nature of problem to be solved, leading inventors to look to references relating to possible solutions to that problem.

[2] Patentability/Validity — Obviousness — Combining references(▶115.0905)

Patentability/Validity — Obviousness — Commercial success (▶115.0908)

Federal district court did not clearly err in concluding that it would have been obvious to combine screw anchors of prior art method with metal brackets used in prior art patents to achieve invention of patents for method of stabilizing or "underpinning" building foundations, even though there was no express written motivation to combine references in prior art, since each cited reference addresses exact same narrow problem of underpinning existing structural foundations, since there is evidence that prior artisans' work showed that screw anchors worked better than straight push piers used in original metal bracket method, and that it was widely known at time of prior art that underpinning system requires means of connecting foundation to load-bearing member, and since record supports court's discounting of defendant's commercial success as evidence of nonobviousness.

Particular Patents

Particular patents — General and mechanical — Building stabilization

5,139,368, Hamilton, Hoyt, Halferty, and Odom, method of underpinning existing structures using screw anchors, judgment of invalidity affirmed.

5,171,107, Hamilton, Hoyt, Halferty, and Odom, method of underpinning existing structures using screw anchors, judgment of invalidity affirmed.

Case History and Disposition

Appeal from the U.S. District Court for the Eastern District of Missouri, Perry, J.

Action by Richard Ruiz and Foundation Anchoring Systems Inc. against A.B. Chance Co. for declaratory

judgment that defendant's patents are invalid and not infringed, and for discrimination pursuant to 42 U.S.C. §1981, breach of contract, breach of implied duty of good faith and fair dealing, promissory and equitable estoppel, and tortious interference with contract and prospective business relations, in which defendant counterclaimed alleging infringement of its patents. District court granted summary judgment for defendant on nonpatent claims, and at trial found that patents were infringed, but that patent claims at issue were invalid for obviousness. Judgment of invalidity was vacated and remanded (57 USPQ2d 1161). On remand, district court again found claims invalid as obvious, and defendant appealed. Affirmed.

Prior decision: 57 USPQ2d 1161.

Attorneys

Matthew A. Rosenberg, of Blumenfeld, Kaplan & Sandweiss, St. Louis, Mo., for plaintiffs-appellees.

John H. Quinn III and Andrew B. Mayfield, of Armstrong Teasdale, St. Louis, for defendant-appellant.

Judge

Before Newman, Michel, and Rader, circuit judges.

Opinion Text

Opinion By:

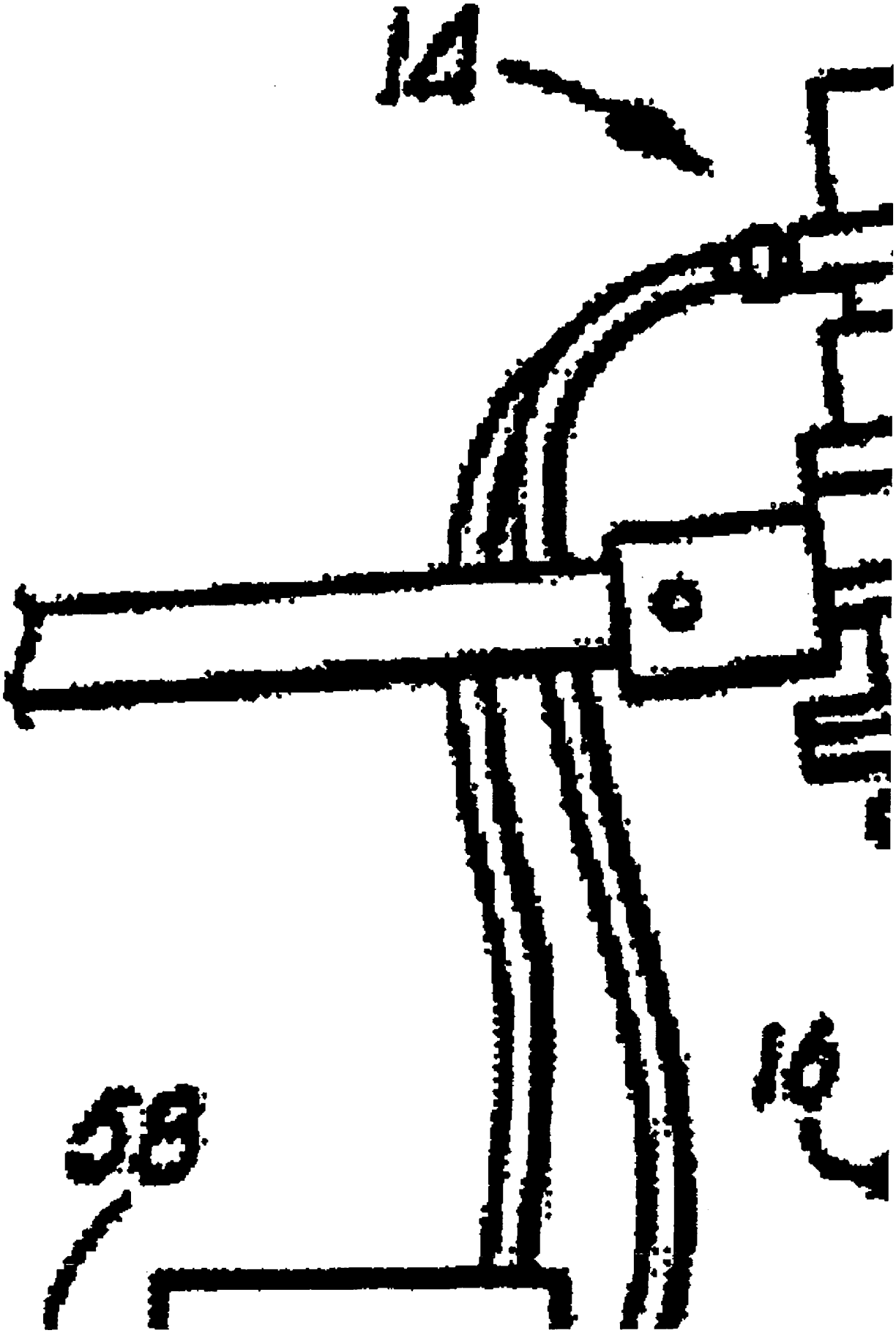
Rader, J.

On remand from this court's decision in *Ruiz v. A.B. Chance Company*, 234 F.3d 654 [57 USPQ2d 1161] (Fed. Cir. 2000), the United States District Court for the Eastern District of Missouri found defendant-appellant A.B. Chance Company's (Chance) patented underpinning system obvious under 35 U.S.C. §103. Because the district court made no clear error in its factual determinations concerning the motivation to combine the prior art teachings and the merit of Chance's asserted secondary considerations, this court affirms.

I.

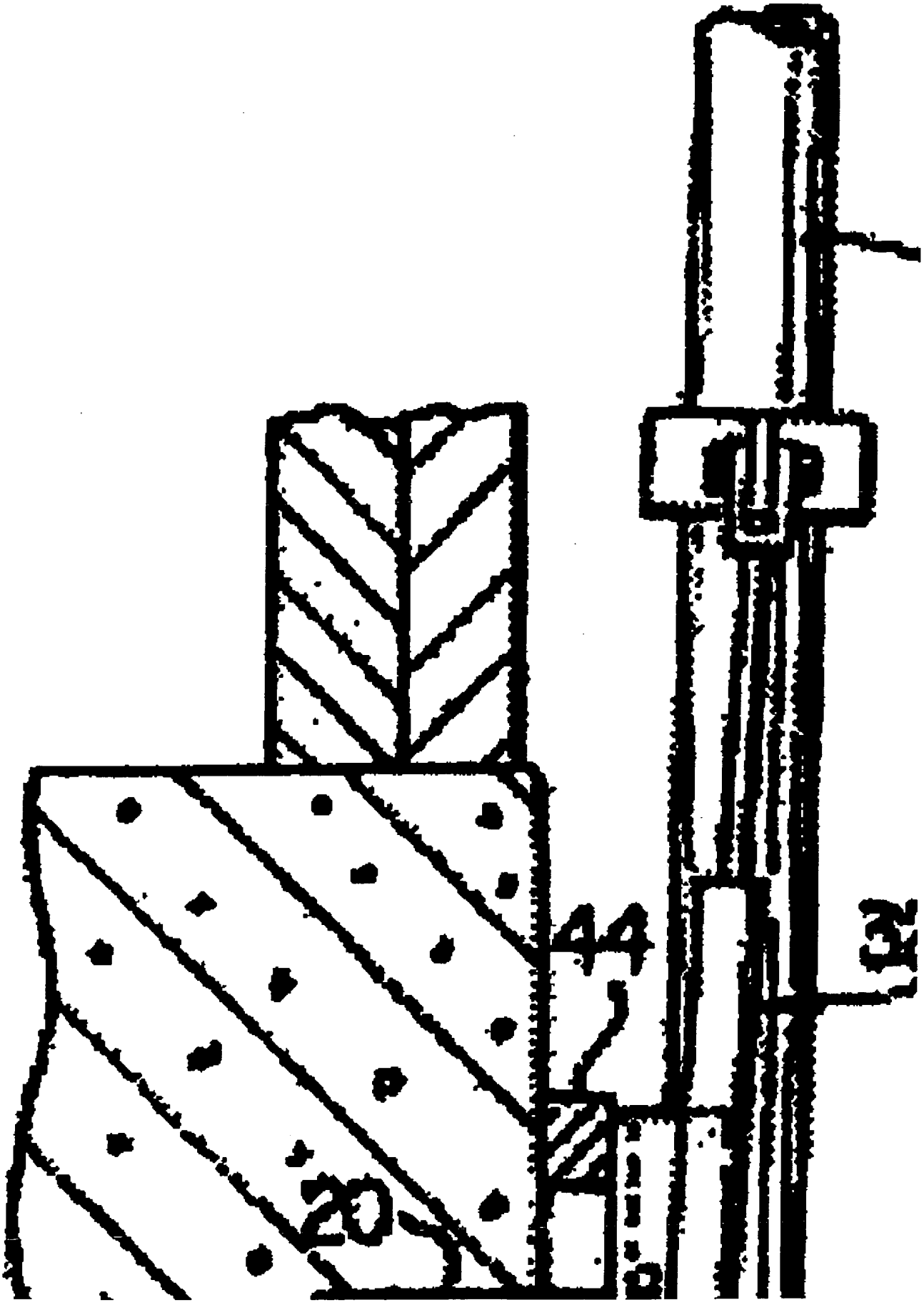
Since about 1970, Chance has manufactured screw anchors, also called helical piers, for use in supporting and stabilizing electrical transmission towers. Screw anchors are elongated shafts with an earth-boring (screw) tip and a transversely extending load-bearing member. In 1988, Chance extended its expertise in stabilizing slumping structures into the residential and commercial building markets. Chance used screw anchors with a metal bracket to underpin these building foundations. The Chance underpinning method places the screw anchor adjacent to the footing and rotates the screw anchor to bore beneath the footing. When resistance to rotation of the screw anchor reaches a specified point, Chance attaches a metal bracket (designated as 30 in the Figure below) to the slouching foundation to transfer the building load onto the screw anchor. The United States Patent and Trademark Office issued U.S. Patent Nos. 5,139,368 and 5,171,107 to Chance in 1992 covering this screw anchor system. Figure 5 in the '107 patent shows the technology:

Page 1688


14
58
16

Appellees Richard Ruiz and his company Foundation Anchoring Systems, Inc. (collectively "Ruiz") became distributors for Chance's underpinning system. During the early 1990s, Ruiz also formed various other anchoring companies and marketed systems that competed with the Chance system. In February 1997, Chance terminated Ruiz's distributorship. Thereafter, Ruiz began marketing an underpinning system with screw anchors and metal brackets. This new system used components from other manufacturers. Ruiz filed suit against Chance in August of that same year alleging various non-patent claims, including discrimination, breach of contract, tortious interference with contract and business relations, and breach of fiduciary duty of good faith and fair dealing. Ruiz also filed for a declaratory judgment that its new underpinning system does not infringe Chance's patents and that the patents are invalid. Chance filed a counterclaim for patent infringement.

The validity question focuses on several prior art references. During the late 1980s, Richard Fuller and Stan Rupiper used screw anchors for underpinning existing structural foundations. Fuller and Rupiper used a concrete haunch, not a metal bracket, to transfer the load of the foundation to the screw anchor (the "Fuller-Rupiper method"). Gregory's U.S. Patent Nos. 4,911,580 and 4,765,777 claim an apparatus and system for underpinning structural foundations using a push pier and a metal bracket. In the Gregory system, the metal bracket transfers the foundation load to the push pier, which is driven into the ground to supply the necessary foundational support. The push pier relies on soil friction to supply that support. Figure 6 of the '580 patent shows this technology:


44
32
20

The scope of the claims in this case is not at issue in this appeal, because the parties agree that the claims are infringed or invalidated by the use of a screw anchor in conjunction with a metal bracket to underpin a foundation. Additional information concerning the claims and the other aspects of this case appear in this court's opinion in *Ruiz v. A.B. Chance Co.*, 234 F.3d 654 [57 USPQ2d 1161] (Fed. Cir. 2000). Examination of the prior art

Page 1689

shows that the Fuller-Rupiper method discloses the screw anchor component of the claims; the Gregory system discloses the metal bracket component in the claims. Thus, this appeal is properly focused on the motivation to combine those teachings, as well as any secondary considerations that might inform the obviousness analysis.

The district court granted summary judgment in favor of Chance on all of Ruiz's non-patent claims in April 1999. On the patent claims, the district court held a *Markman* hearing to construe the claims and a bench trial to decide the issues of infringement and validity. At the time of trial, the scope of the case had narrowed to focus on claims 1-4 and 6-8 of the '368 patent and claims 1-4 and 6-8 of the ' 107 patent. After the trial, the district court entered its judgment from the bench that Ruiz's product infringes the patent claims to the tune of $540,000 in damages. Nonetheless, the trial court determined that the claims are invalid under 35 U.S.C. §103 in light of the Gregory patents and the Fuller-Rupiper method.

This court heard the appeal from that judgment and affirmed every holding of the district court except the finding of obviousness. In *Ruiz*, 234 F.3d at 660, this court remanded the case to the district court for further examination of obviousness. This court issued the following instructions:

> On remand, we instruct the district court to make specific *Graham* findings on: 1) the reason, suggestion, or motivation present in the prior art, in the knowledge of one of skill in the art, or in the problem of foundation settling which clearly and particularly would lead one of ordinary skill in the art to combine screw anchors with metal brackets; 2) the level of ordinary skill in the art; and 3) whether, and to what extent, evidence of secondary consideration, such as commercial success, long felt but unresolved need, failure of others, copying, and unexpected results, is probative in the obviousness analysis.

Id.

The district court invited additional briefing and oral argument on the remand issues. Having reconsidered the evidence of the case, the district court again found the relevant claims invalid as obvious and issued an opinion outlining its factual findings according to this court's instructions. Of particular significance, the district court found the motivation to combine the teachings of the Gregory patents and the Fuller-Rupiper method in the nature of the problem of underpinning foundations itself, explaining:

> The Rupiper method and the Gregory patent can be combined in either of two ways to reach the same result as the method covered by the patents in issue here: by replacing the concrete haunch of the Rupiper method with the bracket of the Gregory patent, or by replacing the straight piling of the Gregory patent with the screw anchor of the Rupiper method. The evidence in this case showed that there was reason, suggestion or motivation to make these combinations. ... The problem is the same: how to underpin an unstable foundation of an existing building.

The district court also discounted Chance's proffered objective evidence of commercial success and skepticism of experts as weak. Specifically, the district court found that the alleged skepticism of Chance's system by Rupiper was merely an acknowledgement that Rupiper's concrete haunch worked better than a metal bracket in seismic areas, such as California. The record indeed does not show that Rupiper doubted that Chance's system would work in general. In addition, the district court attributed Chance's commercial success to its background and experience in screw anchors rather than any inventive features of the screw anchor-metal bracket system as a whole.

Chance now appeals again, arguing that the district court, as it did in its original judgment, employed hindsight to find obviousness. Specifically, this appeal involves two challenges to the district court's obviousness determination: 1) whether the district court clearly erred in finding an implied motivation

to combine the prior art teachings in the nature of the problem of underpinning existing foundations, and 2) whether the district court clearly erred in discounting Chance's evidence of secondary considerations. Jurisdiction over this appeal is proper under 28 U.S.C. § 1295.

II.

Section 103 of title 35 of the United States Code states:

> A patent may not be obtained ... if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.

Page 1690

35 U.S.C. §103(a) (2000).

In making the assessment of differences, section 103 specifically requires consideration of the claimed invention "as a whole." Inventions typically are new combinations of existing principles or features. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 [218 USPQ 865] (Fed. Cir. 1983) (noting that "virtually all [inventions] are combinations of old elements."). The "as a whole" instruction in title 35 prevents evaluation of the invention part by part. Without this important requirement, an obviousness assessment might break an invention into its component parts (A + B + C), then find a prior art reference containing A, another containing B, and another containing C, and on that basis alone declare the invention obvious. This form of hindsight reasoning, using the invention as a roadmap to find its prior art components, would discount the value of combining various existing features or principles in a new way to achieve a new result – often the very definition of invention.

Section 103 precludes this hindsight discounting of the value of new combinations by requiring assessment of the invention as a whole. This court has provided further assurance of an "as a whole" assessment of the invention under §103 by requiring a showing that an artisan of ordinary skill in the art at the time of invention, confronted by the same problems as the inventor and with no knowledge of the claimed invention, would select the various elements from the prior art and combine them in the claimed manner. In other words, the examiner or court must show some suggestion or motivation, before the invention itself, to make the new combination. *See In re Rouffet*, 149 F.3d 1350, 1355-56 [47 USPQ2d 1453] (Fed. Cir. 1998).

While the ultimate determination of obviousness is a legal conclusion reviewed by this court without deference, that determination always entails various factual findings that this court reviews for clear error following a bench trial. *See Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1332 [49 USPQ2d 1001] (Fed. Cir. 1998). The clear error standard permits reversal only when this court is left with a "definite and firm conviction" that the district court was in error. *Amhil Enters. Ltd. v. Wawa, Inc.*, 81 F.3d 1554, 1562 [38 USPQ2d 1471] (Fed. Cir. 1996).

This case deals with a challenge to the district court's conclusion on two of the underlying factual determinations in its obviousness analysis. Accordingly, this court will review for clear error the district court's conclusions regarding objective, secondary considerations, *see Pro-Mold v. Great Lakes Plastics*, 75 F.3d 1568, 1572 [37 USPQ2d 1626] (Fed. Cir. 1996), and whether a motivation to combine the teachings in the prior art references was shown, *see Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1348 [53 USPQ2d 1580] (Fed. Cir. 2000).

The district court in this case presided over a bench trial and reconsidered the evidence on remand. Chance's principal argument is that the district court clearly erred in finding a motivation to combine the teachings in the Gregory patents with the Fuller-Rupiper method. Chance cites this court's precedent that warns district courts about the risk of hindsight reconstruction to find an invention obvious where the invention at issue involves relatively simple technology. *See McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351 [60 USPQ2d 1001] (Fed. Cir. 2001). Accordingly, Chance argues that the district court utilized hindsight to find that a person of ordinary skill would have been motivated to combine the prior art teachings.

[1] To the contrary, the record in this case supports the trial court's findings. While this court indeed warns against employing hindsight, its counsel is just that – a warning. That warning does not provide a rule of law that an express, written motivation to combine must appear in prior art references before

a finding of obviousness. Stated differently, this court has consistently stated that a court or examiner may find a motivation to combine prior art references in the nature of the problem to be solved. *See Pro-Mold*, 75 F.3d at 1573; *Display Techs., Inc. v. Paul Flum Ideas, Inc.*, 282 F.3d 1340, 1346-47 (Fed. Cir. 2002); *In re Huang*, 100 F.3d 135, 139 n.5 [40 USPQ2d 1685] (Fed. Cir. 1996). This form of motivation to combine evidence is particularly relevant with simpler mechanical technologies.

[2] This record shows that the district court did not use hindsight in its obviousness analysis, but properly found a motivation to combine because the two references address precisely the same problem of underpinning existing structural foundations. Moreover the record supports the district court's factual finding that Fuller's and Rupiper's work showed that screw anchors worked better than straight push piers. In fact, the evidence shows that Rupiper introduced Chance to the use of screw anchors in underpinning building foundations. Chance then added a metal bracket to the screw anchor.

Page 1691

The record also supports the district court's conclusion that artisans knew that a foundation underpinning system requires a means of connecting the foundation to the load-bearing member. The Gregory patents teach the use of a metal bracket to connect a foundation to a straight pier, and testimony at trial showed that the need for a connecting element was widely known. Thus, the district court could properly conclude on this record, without being clearly in error, that a person of ordinary skill would be led to combine the screw anchor in the Fuller-Rupiper method with the metal bracket in the Gregory system to underpin an existing building foundation.

This record, it is true, does not feature an express written teaching in the art to make this combination. On this record, however, that is not fatal to the district court's obviousness determination. As noted earlier, this court has repeatedly stated that the motivation to combine the teachings in the prior art may "come from the nature of a problem to be solved, leading inventors to look to references relating to possible solutions to that problem." *Pro-Mold*, 75 F.3d at 1573. The district court in this case applied that settled law. The district court, sitting as a finder of fact, weighed the evidence and found that, because the prior art references address the narrow problem of underpinning existing building foundations, a person seeking to solve that exact same problem would consult the references and apply their teachings together. Thus the district court's conclusion is perfectly legitimate when the evidence supports it, as it does here.

Chance's argument amounts to little more than its own alternative view of the evidence. While the record does contain some evidence against the district court's finding, such evidence is not overwhelming by any means. In addition, the district court in this case did not simply discount all contrary evidence and bolster a meager amount of evidence to reach a preformed conclusion. In fact, the district court discounted and discredited some testimony that actually supported its ultimate conclusion. For instance, the trial court dismissed the testimony of Robert Jones, a Chance distributor, that he would have made the combination. The district court declined to credit Mr. Jones' testimony because he exhibited far more than an ordinary level of skill in this art. The trial court's careful consideration of Mr. Jones' evidence shows further that it performed a detailed and reasoned analysis of the evidence, rather than a conclusion-oriented discussion that typically accompanies a hindsight analysis. In short, the record in this case does not approach the evidence necessary to leave this court with a firm conviction that the district court committed clear error in its factual finding of a motivation to combine the Fuller-Rupiper and Gregory teachings.

Finally, the record also supports the district court's discounting of Chance's evidence of secondary considerations. The record supports the trial court's finding that any commercial success was not due to Chance's alleged unique combination, but rather due to Chance's experience with screw anchors combined with being the first large screw anchor manufacturer to enter the underpinning market. The district court did not clearly err in reaching this conclusion, nor in concluding that the evidence of skepticism was weak.

III.

Based on the above analysis, this court holds that the district court did not clearly err in finding a motivation to combine the prior art references in the nature of the problem at issue. In addition, this court holds that the district court did not clearly err in discounting Chance's evidence of secondary considerations. Accordingly, this court affirms the judgment of the district court.

COSTS

Each party shall bear its own costs.

AFFIRMED

- End of Case -

ISSN 1526-8535